OVERVIEW

We are a biopharmaceutical company with an integrated platform for product development and commercialization. We strategically focus on some of the largest and fast-growing therapeutic areas with significant unmet medical needs in China, primarily including oncology and severe infection. Leveraging our integrated platform, we strive to develop and commercialize a portfolio of high-quality marketed products, including our proprietary product, Zadaxin, and pipeline drugs in our focused therapeutic areas.

Primary therapeutic area focus:

- **Oncology**: For details of the oncology market, see "Industry Overview — Oncology Market." Amongst other clinical adoptions, our proprietary product, Zadaxin, has been listed in the treatment guidelines for the treatment of liver cancer, pancreatic cancer and lymphoma, and the incidences of such cancers are expected to constantly increase in the near future. According to Frost & Sullivan, the incidence of liver cancer in China was 410.4 thousand in 2019, and is expected to reach 462.8 thousand in 2024 and 526.0 thousand in 2030, representing a CAGR of 2.4% from 2019 to 2024 and a CAGR of 2.2% from 2024 to 2030; the incidence of pancreatic cancer in China was 108.4 thousand in 2019, and is expected to reach 127.1 thousand in 2024 and 152.2 thousand in 2030, representing a CAGR of 3.2% from 2019 to 2024 and a CAGR of 3.0% from 2024 to 2030; the incidence of lymphoma in China was 95.4 thousand in 2019, and is expected to reach 107.1 thousand in 2024 and 121.6 thousand in 2030, representing a CAGR of 2.4% from 2019 to 2024 and a CAGR of 2.1% from 2024 to 2030.
- **Severe infection**: According to Frost & Sullivan, infectious diseases are currently the second largest therapeutic area in China. Our proprietary product, Zadaxin, has been indicated for the treatment of hepatitis B, and has been listed in the treatment guidelines for the treatment of COVID-19 and sepsis. The increasingly challenging treatment of complex severe infection diseases has generated unmet medical needs, leading to promising market potentials. See "Industry Overview."

Our products and services:

We have a high-quality portfolio of marketed products, including our proprietary product, Zadaxin. Over the past decades, Zadaxin has gained recognition among doctors and patients as a trusted branded product, especially for its potential benefits in treating SARS and COVID-19 as suggested by clinical case series from retrospective studies accepted by peer-reviewed academic journals including *Cell Research, Herald of Medicine*, *Chinese Critical Care Medicine* and *Chinese Journal of Medical Imaging Technologies*. As a result, Zadaxin has been listed for the treatment of severe and critical cases of COVID-19 in the treatment guideline issued by the NHC and the State Administration of Traditional Chinese Medicine. Zadaxin has demonstrated market potential, evidenced by its sustainable revenue growth through challenges, including generic competition, changes in reimbursement policies and changes in the centralized tender processes. Our in-licensed products include Angiomax and Zometa. We also sell promotion products for our partner

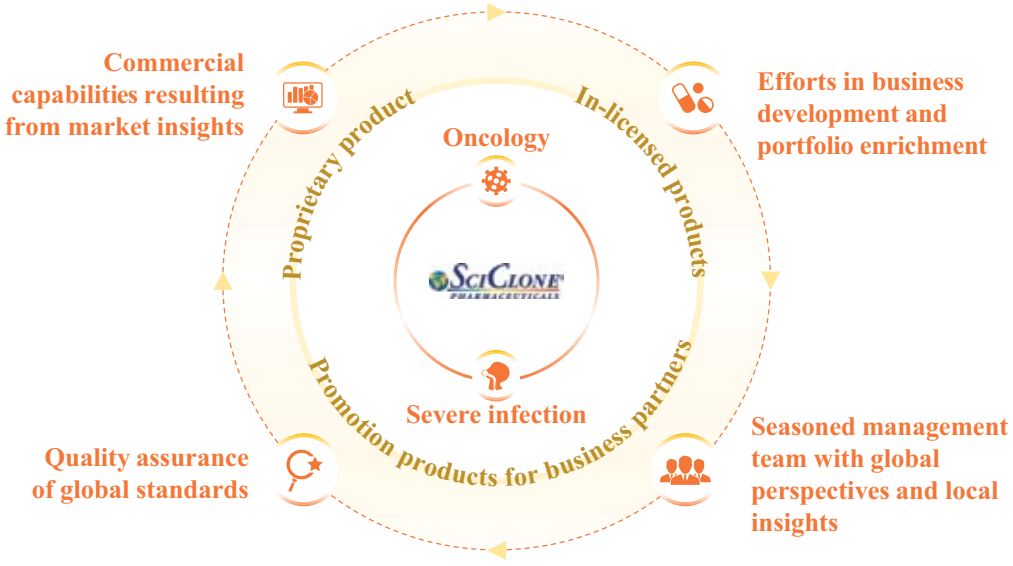
pharmaceutical companies, such as Pfizer and Baxter. In addition, we have built a pipeline of in-licensed early- to late-stage drug candidates.

Our core competencies:

Our four core competencies have strengthened our leading market position and sustained our financial success.

- **Commercial capabilities resulting from market insights**: Our commercial capabilities underpin our success. Our cohesive sales and marketing team consists of highly experienced personnel with industry knowledge, who are able to timely respond to market dynamics, improve operational efficiency and enhance customer experiences. Driven by our market insights, our commercialization initiatives enable us to capture industry and policy trends. As a result, we remain highly nimble in adopting innovative business models, including the online Go-To-Patient ("GTP") platform which has successfully extended our sales beyond hospitals into pharmacies and ensured our sustainable growth despite challenges.
- **Efforts in business development and portfolio enrichment:** Through the close collaboration across our business development, clinical development and regulatory affairs teams, and leveraging our strong relationship with leading KOLs in our commercialization network, we have benefited from our efforts in enriching our product portfolio by identifying and commercializing product candidates with market potential, thereby establishing a product pipeline of in-licensed early- to late-stage drug candidates covering high potential therapeutic areas. Our efforts in portfolio enrichment, coupled with lifecycle management, resulted in the successful expansion of the clinical adoptions of Zadaxin.
- **Quality assurance of global standards:** Our quality assurance system is commensurate with the global standards of compliance of our MNC partners. It minimizes our operational risk and safeguards our sustainable growth, making us stand out as a biopharmaceutical company with high-quality products, a go-to partner of pharmaceutical MNCs and a valued and reliable source of long-term return for investors.
- **Seasoned management team with global perspectives and local insights:** Core members of our management team have, on average, more than 20 years of experience in the pharmaceutical industry. They lead our business operations with global perspectives sharpened by extensive managerial experience in pharmaceutical MNCs, and local insights accumulated through decades of groundwork with hospitals, doctors, pharmacies and patients in China.

The chart below sets forth our primary focused therapeutic areas, the products and services we provide, and our core competencies:



Based on our core competencies, we have achieved strong financial results during the Track Record Period. In 2017, 2018 and 2019, and the nine months ended September 30, 2019 and 2020, our revenue was RMB1,213.0 million, RMB1,408.9 million, RMB1,708.1 million, RMB1,290.8 million and RMB1,584.2 million, respectively, representing a CAGR of 18.7% from 2017 to 2019, while our profit was RMB19.6 million, RMB535.1 million, RMB614.6 million, RMB487.2 million and RMB689.8 million, respectively.

Marketed Products

	Product Name	Mechanism of Action	Indication(s)	Originator / Partner	Commercial Rights
Proprietary	Zadaxin® (thymalfasin)	Immunomodulator of thymalfasin	Cancers / infectious diseases	–	Proprietary asset
License-in	Zometa® (zoledronic acid)	Osteoclast-mediated bone resorption inhibitor	Bone metastases from solid tumors	Novartis (Switzerland)	Permanent right to commercialize in Mainland China IP acquired or licensed
Promotion products for business partners	Farlutal (Medroxyprogesterone Acetate)	Gonadotropin inhibitor	Cancers	Pfizer (USA)	Promotion services and distribution through 2022 for renewal
	Methotrexate	DHFR inhibitor Nuclear estrogen receptors and DNA synthesis reducer	Acute leukemia / cancers		
	Estracyt (Estramustine Phosphate)	DNA alkylator	Hormone resistant advanced prostate cancer		
	Holoxan (Ifosfamide)	DNA and protein synthesis inhibitor	Cancers	Baxter (USA)	Promotion services and distribution through 2022 for renewal
	Mesna (Sodium-2-mercaptoethane Sulfonate)	Organosulfur compound used as an adjuvant in cancer chemotherapy to detoxify urotoxic metabolites	Urotoxicity		
	Endoxan (Cyclophosphamide)	Protein synthesis inhibitor through cross-linking of DNA and RNA	Cancers		

Abbreviations: DHFR = Dihydrofolate Reductase; DNA = Deoxyribonucleic Acid; PCI = Percutaneous Coronary Intervention; RNA = Ribonucleic Acid

Notes:

(1) As of the Latest Practicable Date, Zometa was sold through the existing distribution network by Novartis in several provinces in China, and we recognized other income from Zometa through our licensing arrangement with Novartis to receive profit transferred from Novartis for the sales of Zometa. We also started recognizing revenue from our sales of Zometa since December 2020 as we began distributing Zometa in certain provinces in China. In January 2021, we completed the transfer of IDL for Zometa, and became the MAH of Zometa in the PRC.

(2) As of the Latest Practicable Date, all of these marketed products were covered by the centralized tender process, and none of these marketed products was covered by the volume-based procurement. See "Regulatory Overview — Drug Purchase by Hospitals."

(3) As of the Latest Practicable Date, Holoxan, Mesna and Endoxan were listed in the National Essential Drug List. See "Regulatory Overview — National Essential Drug List."

Product to be Marketed

	Product Name	Mechanism of Action	Indication(s)	Originator / Partner	Commercial Rights
License-in	Angiomax® (bivalirudin)	Anticoagulant for PCI	Percutaneous transluminal coronary angioplasty Percutaneous coronary intervention	The Medicines Co. (USA)	Permanent right to commercialize in Mainland China IP licensed

Note:

(1) We entered into a Product Promotion Agreement with Huizheng on August 31, 2020, under which Huizheng was engaged for the promotion and distribution of our in-licensed product Angiomax in Mainland China. Angiomax is expected to be commercialized in the first quarter of 2021.

Pipeline Products

	Product Name	Mechanism of Action	Indication(s) / Clinical Adoptions	Partner	Date of Partnership Commencement	Commercial Rights	Our Contribution in China	Pre-Clinical / IND Filing / Phase I / Phase II / Phase III / NDA/BLA Filing / Marketed
Late-Stage	Oravig [1]	Lanosterol 14 α - demethylase inhibitor	Oropharyngeal candidiasis	Vectans Pharma (France)	June 2, 2008	10-year license from the date of first commercial sales in Mainland China, Hong Kong and Macau	Completed the phase III trial and obtained NMPA approval for commercialization	Marketed (Vectans Pharma); Commercialization expected in Q3-2021
Late-Stage	Vibativ (telavancin) [2]	Dual antibacterial activity on cell wall and cell membrane	HABP/VABP complicated skin and skin structure infections	Cumberland Pharma-ceuticals (USA)	May 21, 2015	15-year license from the date of first commercial sales in Mainland China, Hong Kong, Macau, Taiwan and Vietnam	Obtained IND and clinical trial waiver	Marketed (Cumberland Pharmaceuticals); Clinical trial waiver obtained; NDA submission expected in Q3-2021
Late-Stage	RRx-001 [3]	Myc inhibitor and antagonist of CD47-SIRPα pathway	Small cell lung cancer Colorectal cancer	EpicentRx,Inc. (USA)	June 30, 2020	10-year license from the date of first commercial sales in Mainland China, Hong Kong, Macau and Taiwan	Pre-IND conducted and in preparation of IND filing	US Phase III trial ongoing (Soligenix); US Phase III trial completion expected by the end of 2021 Combo with Irinotecan; US Phase II trial completed and Phase III trial launch expected in Q2-2021
Late-Stage	Naxitamab	Targeting GD2	High risk neuroblastoma	Y-mAbs Therapeutics, Inc. (USA)	December 17, 2020	license of an indefinite term from December 17, 2020 in Mainland China, Hong Kong, Macau and Taiwan	-	US Phase I and Phase II trials completed (Y-mAbs); Received approval fromFDAon BLA in November 2020 [6]
Late-Stage	Omburtamab	Targeting B7-H3–expressing cells	CNS/ leptomeningeal metastasis from neuroblastoma	Y-mAbs Therapeutics, Inc. (USA)	December 17, 2020	license of an indefinite term from December 17, 2020 in Mainland China, Hong Kong, Macau and Taiwan	-	US Phase I and Phase II trials completed (Y-mAbs); Y-mAbs plans to refile BLA for Omburtamab in early 2021 [6]
Early Stage	PEN-866 [4]	Mini-conjugate of HSP90-SN38	Solid tumors	Tarveda Therapeutics (USA)	March 17, 2020	20-year license from March 17, 2020 in Mainland China, Hong Kong, Macau and Taiwan	-	US Phase II basket trial ongoing (Tarveda Therapeutics); US Phase II trial completion expected in Q4-2022
Early Stage	PT-112	Platinum-containing compounds	Late stage prostate cancer Cholangiocarcinoma	Phosplatin Therapeutics (USA)	May 26, 2015	15-year license from the date of first commercial sales in Mainland China, Hong Kong, Macau and Vietnam	Completed phase I and initiated phase II trial	US Phase II trial ongoing (Phosplatin Therapeutics); US Phase II trial completion expected in Q4-2021 Combo with Gemcitabin; Phase II trial completion expected in Q4-2022
Early Stage	ABTL-0812	Akt/mTOR inhibitor	Endometrial cancer lung cancer pancreatic cancer	Ability Pharma (Spain)	April 22, 2016	15-year license from April 22, 2016 in Mainland China, Hong Kong, Macau, Taiwan and Vietnam	Obtained IND	EU Phase II trial ongoing (Ability Pharma); EU Phase II trial ongoing

China status [5] | Partner's overseas status [5] | Intend to utilize overseas clinical data for the NDA application in China

Abbreviations: Akt = Protein Kinase B; HABP = Hospital-acquired Bacterial Pneumonia; HSP90 = Heat Shock Protein 90; mTOR= Mammalian Target of Rapamycin; SN38 = 7-ethyl-10-hydroxycamptothecin; VABP = Ventilator-associated Bacterial and Pneumonia

Notes:

1. Our partner conducted Phase III and the earlier phases of the clinical trials. We obtained clinical waiver for clinical trials in China, and intend to conduct a bridging study for approval.
2. We conducted Phase III of the clinical trials, and our partner conducted the earlier phases of the clinical trials.
3. We expect to participate in the China portion of Phase III MRCT (Multi-Regional Clinical Trials) for Small Cell Lung Cancer in 2021 with EpicentRx.
4. We intend to join China portion of Phase III MRCT with Tarveda.
5. We are responsible for the clinical trials in China. Our partners are responsible for the clinical trials overseas.
6. Naxitamab and Omburtamab, both being biological products, are required to obtain BLA approval before commercialization. For both products, a Phase II clinical trial is adequate to serve as a pivotal trial in support of a BLA approval. As a result, as of the Latest Practicable Date, no Phase III clinical trial was intended or would be carried out for Naxitamab and Omburtamab.

OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors:

A product portfolio focusing on high-potential therapeutic areas, led by marketed products with strong cash generation ability and effective lifecycle management, and fueled by pipeline products, to drive sustainable growth

We have captured the enormous opportunities in the oncology and severe infection markets in China, the two primary therapeutic areas that we strategically focused on. According to Frost & Sullivan, oncology is the fastest growing major therapeutic area in China. The oncology drug market in China grew at a CAGR of 13.5% from 2015 to 2019 and is expected to be the largest therapeutic area in China's pharmaceutical market in 2024, with an CAGR of 15.0% from 2019 to 2024. Infectious diseases are currently the second largest therapeutic area in China. In particular, severe infection demonstrates promising market potential. We selectively expand our product portfolio focusing on such therapeutic areas to outperform the market. From 2017 to 2019, our revenue grew from RMB1,213.0 million in 2017 to RMB1,708.1 million in 2019, representing a CAGR of 18.7%, while the overall China's pharmaceutical market, according to Frost & Sullivan, grew at a CAGR of 6.9% during the same period.

We have achieved sustainable revenue growth, driven by Zadaxin as a trusted branded product, which we believe will continue to succeed. With its market leadership, Zadaxin has continued to gain market share from generics. According to Frost & Sullivan, its market share grew from 44.1% of the thymalfasin market in China in terms of sales revenue in 2015 to 57.5% in 2019. Furthermore, our successful lifecycle management of Zadaxin has led to the expansion of its clinical adoptions. Zadaxin is included in the treatment guidelines issued by the NHC and several professional associations including the Chinese Medical Association and the Chinese Society of Clinical Oncology ("CSCO"), for the treatment of sepsis, pancreatic cancer, liver cancer, and COVID-19, leading to strong demand for Zadaxin. In 2017, 2018, and 2019, and the nine months ended September 30, 2019 and 2020, our revenue generated from Zadaxin was RMB1,112.6 million, RMB1,168.8 million, RMB1,349.3 million, RMB1,035.1 million, and RMB1,326.3 million, respectively. See "— Products and Services — Our Proprietary Product — Zadaxin 日达仙." Besides Zadaxin, Angiomax and Zometa are also poised to succeed. See "— Products and Services — Our In-licensed Products." Moreover, we generate substantial revenue from sales of promotion products for Pfizer and Baxter in China, constantly gaining market shares from generics. See "— Products and Services — Our Sales of Promotion Products for Business Partners." Our product lifecycle management capabilities have made us the attractive partner for pharmaceutical MNCs in China.

In addition to our marketed products, we also strive to source assets that synergize with our existing product portfolio, focusing on areas with significant unmet medical needs. As of the Latest Practicable Date, we had a pipeline of eight drug candidates, including five late-stage drug candidates, namely, Oravig, Vibativ, RRx-001, Naxitamab and Omburtamab, and three early-stage ones, namely, PEN-866, PT-112 and ABTL-0812. RRx-001 is a well-tolerated next-generation small

molecule immunotherapeutic that targets the CD47-SIRPα axis, repolarizes tumor associated macrophages and other immunosuppressive cells, and improves tumor blood flow to enhance oxygen supply and drug delivery. It has the potential to convert treatment-resistant tumors into treatment-sensitive tumors and may have wide clinical adoptions as monotherapy or in combination with chemotherapy, immunotherapy, radiation and targeted agents. PEN-866 is the first-in-class small molecule drug conjugate that preferentially binds to the activated form of HSP90 in solid tumors and is linked to the topoisomerase 1 inhibitor (SN-38), a potent anti-cancer payload. As the SN-38 payload is cleaved in the tumor over time, the sustained release of SN-38 in the tumor results in prolonged DNA damage and tumor regressions as demonstrated in multiple patient-derived and other xenograft tumor models.

Product commercialization in China driven by innovation and evidenced by a proven track record

Our strong and proven commercialization capabilities distinguish us from our competitors and drive our sustainable profitability. The capabilities are built upon our market coverage initiatives, stakeholder engagement and effective sales force.

We have adopted a "Go Deeper and Broader" strategy based on our market insights to strengthen the coverage of our products for hospitals, pharmacies and other medical institutions. We "go deeper" by adopting targeted programs to further penetrate covered hospitals and hospital departments in order to improve the accessibility of our products to patients. We "go broader" by expanding our geographic footprints to new cities, hospitals and hospital departments to reach new patients. Instead of a cover-all approach with high costs and uncertainty, we have capitalized on our market and product insights to allocate resources in an efficient manner, contributing to sustainable profitability. As of September 30, 2020, our distribution network through Sinopharm for Zadaxin had reached approximately 1,130 class III hospitals, approximately 1,250 class II hospitals, approximately 720 pharmacies and approximately 3,560 other medical institutions in China, and our distribution network for the sales of promotion products for business partners had reached approximately 1,170 class III hospitals, approximately 2,020 class II hospitals, approximately 160 pharmacies and approximately 1,610 other medical institutions in China, with a sales and marketing team of 616 members. We believe our market coverage initiatives enable us to successfully concentrate our resources on those chosen market segments with strong potential to deliver promising long-term performance.

We strive to innovate our sales models and processes through digitalization, with a view to improving our operational efficiency and patient experience through enhanced stakeholder engagement. This is exemplified by our adoption of the Go-To-Patient ("GTP") model, which potentially enhances not only communication between doctors and patients outside traditional hospitals, but also our diversity of sales channels and direct reach to patients. Collaborating with Sinopharm, in order to diversify our sales channels and promote Zadaxin's sales to patients through pharmacies, we piloted our GTP platform in 2015 which has since enhanced Zadaxin's accessibility to patients by extending its sales beyond hospitals to pharmacies. We commenced to generate sales through this platform from 2018. In 2018, 2019, and the nine months ended September 30, 2020,

sales volume through our GTP model accounted for more than 20%, more than 30% and more than 50% of our total sales volume of Zadaxin, signifying the increasing accessibility of Zadaxin to patients through pharmacies. See "—Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China — Innovative Model: Go-To-Patient (GTP) strategy and platform." With our multi-channel reach of patients, doctors and other stakeholders, we are able to timely respond to market dynamics and enhance customer experience.

We strive to recruit sales force among the most qualified candidates, seeking individuals who are experienced, committed, and well-equipped to tackle complex challenges. A majority of our senior sales managers have experiences working in MNCs, and our sales directors have on average approximately 18 years of industry experiences. Our sales force, especially for members at managerial level, has remained stable with low attrition rate, which ensures the consistency in the performance. We proactively consolidate the strengths of our different functional teams through our Area Alignment Committee to realize close cross-functional collaboration. See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China — Our Sales and Marketing Force."

Our strong commercialization capabilities are evidenced by our proven track record. For Zadaxin, we have successfully demonstrated the ability to gain market share from generics. According to Frost & Sullivan, the market share of Zadaxin increased from 44.1% in 2015 to 57.5% in 2019 in the thymalfasin market in China, in terms of sales revenue. Our successful track record in commercialization has also made us the partner of choice for pharmaceutical MNCs to commercialize their products in China. As a long-term partner for Pfizer and Baxter, we have delivered solid performance, including gaining market shares from generics for our partners' established products. For example, according to Frost & Sullivan, the market share of Methotrexate, which we sell for Pfizer, in the methotrexate injection market in China grew from 37.3% in 2015 to 81.9% in 2019, in terms of sales revenue.

Efforts in business development and portfolio enrichment to build a drug pipeline that addresses unmet medical needs

Our success is also attributable to our efforts in business development and portfolio enrichment. We not only have a focused business development and portfolio enrichment strategy, but also benefit from the insights gained from the collaboration with doctors that we connect through our commercialization network.

We have adopted a clear portfolio construction strategy and aim for a strong market position in high-value and high-growth therapeutic areas with significant unmet medical needs in China, such as oncology and severe infection. Our portfolio construction strategy emphasizes on market potential, efficacy and acceleration in the products development process. We are committed to sourcing potential best- and first-in-class products from biotech companies globally.

Our portfolio enrichment benefits from the close collaborations across our business development, clinical development, and regulatory affairs teams, and the relationships established

through our commercialization network with other stakeholders. Our business development team is able to make quick decisions in identifying potential assets that synergize with our existing product portfolio, and manage relationship with our licensing partners. The clinical development team works closely with the business development team to assess new asset opportunities. With established connections with reputable investigators, our clinical development team has a proven track record in maximizing assets' commercial potential with accelerated development plan. Our regulatory affairs team consists of seasoned professionals with extensive experiences in handling regulatory affairs and in-depth knowledge in China's pharmaceutical regulatory framework. Our business development, clinical development, and regulatory affairs teams, supported by the strong relationships with other stakeholder established by our sales force, collaborate to accelerate our product development process, maximizing the probability of our products to successfully reach the market.

Through the efficient execution of our product development strategy and the interaction between our product development teams and doctors, we are able to generate a portfolio of de-risked late-stage product candidates such as Oravig and Vibativ, and early-stage and next-generation assets, such as PEN-866, PT-112 and ABTL-0812, for further clinical development. See "— Product Development."

Strong brand image underpinned by quality assurance of global standards

Our strong brand image is underpinned by our quality assurance of global standards, which minimizes our operational risk, safeguards our sustainable growth and makes us a reliable source of long-term return for investors. Our commitment to quality assurance is exemplified by our culture of "high compliance and high performance," our infrastructure that ensures compliance, and our strict implementation of such standards in daily operations. Such vigorous pursuit has earned us reputation as a provider of top-quality products and a go-to partner of pharmaceutical MNCs.

We pride ourselves with the culture of "high compliance and high performance." As a former NASDAQ-listed company, we are well endowed with the culture of "high compliance" for public companies, and we uphold our operations to, and have benefited from, such culture after our privatization. We are trusted by patients and doctors across China and by pharmaceutical MNCs as a long-term business partner, due largely to our pursuit of "high compliance."

Our internal policies and SOPs ensure that our internal control is commensurate with the global standards of our MNC partners. See "— Internal Control and Risk Management." Our integrated quality management infrastructure ensures that our products are in full compliance with our quality control standards. See "—Production and Quality Control — Quality Management." We manage our daily operations, monitor our product quality and oversee CMO compliance based on our internal control system. We actively engage in external audits conducted by our pharmaceutical MNC partners, to ensure that our operations meet stringent quality assurance and internal control requirements. We also carefully select our business partners among reputable companies with stringent quality assurance and internal control standards.

We have demonstrated a strong track record of quality assurance. As part of our ordinary course of collaboration arrangements with our business partners, we participate in the due diligence

audits by our business partners to demonstrate our commitment to compliance and to strengthen the business relationship. Since 2016, we have successfully passed four external audits by our pharmaceutical MNC partners, including one audit by Pfizer in 2018, one audit by Baxter in 2020, and two audits by BTG plc regarding our previous DC Bead product in 2016 and 2019, respectively. Such recognition by global industry leaders is enjoyed by few of our peers. We believe our high standards have earned us esteemed reputation and trust from our customers and business partners. Our commitment to quality assurance of global standards not only distinguishes us from our competitors, but also enables us to outperform the market.

A visionary management team with a successful track record in the pharmaceutical industry

Our core management team comprises seasoned pharmaceutical industry professionals, with vision and proven execution capabilities. Members of our core management team have, on average, more than 20 years of experience in the pharmaceutical industry, a significant portion of which worked with pharmaceutical MNCs, such as Novartis, Roche, Johnson & Johnson and Bristol Myers Squibb. They have gained in-depth knowledge and extensive expertise covering all stages of pharmaceutical lifecycle management and all processes of the pharmaceutical industry value chain, encompassing clinical drug development, regulatory affairs, supply chain management, quality control, sales, marketing and commercialization. In particular, we are led by our President and CEO, Mr. ZHAO Hong, who has gained extensive leadership and managerial knowledge through over 30 years of experience working in the medical and pharmaceutical industry. Prior to joining our Company, Mr. ZHAO Hong worked as executive vice president of Simcere Pharmaceutical Group and as senior vice president of Beijing Novartis Pharmaceutical Co., Ltd. In addition, our business units, our product development teams, and our functional groups (such as finance, human resources, legal, and information technology) are all led by experienced industry professionals with respective expertise. See "Directors and Senior Management."

The valuable experience and vision of our management team is consonant with that of our employees'. Our employees represent the top talent in the industry. With our corporate structure that delivers transparency and efficiency, our decision chain from the management to execution is delayered with efficient communication and clear accountability. We grow together with our employees and aim for higher retention and lower attrition rate. Our competitive compensation schemes, including employee stock ownership plans, enhance the sense of ownership and belonging of our employees.

We are also backed by strong endorsement from our investors, such as GL Capital Group, CDH Investments, Ascendent Capital Partners, and BOC Group. Since our privatization, our investors have provided us with strategic inputs in areas such as business development, corporate governance and internal control, which have continuously benefited our operations.

OUR STRATEGIES

We intend to carry out the following key strategies:

Continue to strengthen our marketed product portfolio through effective lifecycle management

We intend to maintain our robust revenue growth and strong cash flow through effective lifecycle management of our marketed products. For Zadaxin, we are conducting clinical studies to expand its clinical adoptions in oncology, severe infection, vaccine and other therapeutic areas. Key directions of such clinical studies include:

- **Oncology**: discovering potential combination of Zadaxin with PD-1 or PD-L1 inhibitors for treatment of gastric cancer; discovering potential combination of Zadaxin with innovative anti-cancer small molecules to complement chemotherapy; and sponsoring investigators to conduct randomized controlled trials (RCT) and real-world studies (RWS) to discover Zadaxin's potential clinical adoptions for treatment of liver cancer and lung cancer;
- **Severe infection**: conducting RCT and RWS in China and filing for IND application with the FDA for clinical trials in the U.S. to discover Zadaxin's potential treatment of COVID-19; conducting studies of the effect of thymosin alpha 1 ("Tα1") on preventing COVID-19 infection of elderly renal dialysis patients and treatment of severe COVID-19 patients in the U.S.; conducting studies on the potential expansion of Zadaxin's indication to sepsis; and researching on Zadaxin's potential treatment of associated acute-on-chronic liver failure (ACLF);
- **Vaccine and other therapeutic areas**: conducting RWS in China in collaboration with local CDCs to evaluate Zadaxin's therapeutic effect as COVID-19 vaccine adjuvant; conducting international clinical research projects to discover immunomodulatory effect of Tα1 on cancers; and conducting studies with international researchers on Zadaxin's potential effect on cystic fibrosis.

We will continue to accumulate clinical evidence through RCT and RWS and to expand our participation in domestic and international clinical research projects for the expansion of Zadaxin's clinical adoptions. We closely monitor market trends related to COVID-19 and other vaccine research projects to capture the opportunity of utilizing Zadaxin as adjuvant for future vaccines.

For Zometa, we will accumulate more clinical evidence through RWS for potential clinical adoptions and build up its brand awareness to achieve wider market acceptance. In addition, we plan to expand the network coverage of Zometa to more hospitals and other medical institutions in China. We expect the sales of Zometa to account for a significant and increasing share of our revenue in the near future. For Angiomax, we cooperate with partners with strengths and focus on commercialization of cardiovascular disease products for its promotion and sales.

We will continue to focus on Mainland China, particularly on class III and class II hospitals and pharmacies through which we believe we could attract more target patients. While we further

develop and strengthen our presence in China's market, we will also explore potential opportunities to cooperate with global partners, including those in South Korea, Italy, and the U.S. We will leverage our existing approval and licensing resources to develop local partnerships in jurisdictions where we are authorized to sell our products. In addition, we intend to further expand into new markets with broad and comprehensive commercial medical insurance coverage. Our team will support and drive protocol design with KOLs in geographic areas with approved indications, such as Italy and the U.S., to further promote our brand and product awareness and acceptance in the global markets.

Optimize our pipeline with accelerated fast-to-market strategy for late-stage assets and potential first/best-in-class focus for early-stage assets

We have a clear portfolio construction strategy with strong positioning in high-value and high-growth therapeutic areas primarily including:

- **Oncology**: We actively seek to develop and commercialize products focusing on targeted therapies, immunotherapy and enhanced chemotherapy options with first/best-in-class potential. For instance, our pipeline products RRx-001 and PEN-866 have substantial potential in future market development. We also intend to bring in potential candidates that are able to enhance the current cancer treatment and chemotherapy formulation with better efficacy and safety profile; and
- **Severe infection**: We focus on products with proven efficacy on severe infection caused by resistant bacteria environment, especially those cases caused by cross-contamination in the ICU and other hospital settings. Such products have strong potential due to substantial unmet needs from the patients.

We intend to further develop potential first/best-in-class products in oncology and severe infection areas by seeking global partnership with renowned pharmaceutical MNCs and leveraging our expertise in such therapeutic areas. We focus on products with reliable efficacy and market potential. We explore collaboration on in-licensing new drug candidates which potentially complement and synergize with our existing marketed and pipeline products, such as new immuno-oncology agents, and new small molecule agents that can be combined with chemotherapy and immuno-oncology for better efficacy and safety profile. We also actively seek candidates that meet clinical trial waiver conditions based on our industry experience and market insights to accelerate the development process and save relevant costs which may be otherwise incurred in clinical trials.

Leveraging our established commercial platform, we intend to accelerate the market acceptance for our newly launched products. For Vibativ, which has potential demands from patients with severe infection, especially infection from the ICU, we intend to market through our existing hospital coverage to fast-track its recognition in the target market. For Oravig, which has more potential demand from patients through retail channels, we intend to utilize our existing retail sales channels in our target markets and provide one-stop consultation and prescription services to the patients through our GTP model. We have customized strategies for different therapeutic areas for different target patient groups, fully realizing the potential of our commercial platform and accelerating our product acceptance in the target markets.

We intend to accelerate our new product development for early-stage candidates with progressive development strategies. We identify the suitable direction for indication clinical studies of the candidates through analyzing unmet clinical needs. We seek accelerated approval opportunities for the candidates to save costs and time. We also intend to take advantage of the recent regulatory update that shortened registration timeline in China for products conducting MRCT in multiple countries by collaborating with our overseas partners. For our pipeline product RRx-001, we have collaborated with EpicentRx and plan to conduct the Phase III MRCT both in China and the United States for potential third-line therapy and beyond for small-cell lung cancers, which currently have relatively few third-line or beyond therapies available.

Continue to innovate in business model and enhance our commercialization and development capabilities

We have successfully developed our GTP model. GTP has contributed significantly to the sales growth of Zadaxin through its expansion into the retail channels. We believe we can effectively extend the GTP model to our other current and pipeline products with relatively low additional costs. We intend to prioritize the implementation of the GTP model on products with more retail patient needs, such as Oravig, and products with recurring patient prescription needs. For the nine months ended September 30, 2020, sales through our GTP model contributed to more than 50% of our total sales volume of Zadaxin, and we expect our sales from retail channels to account for an increasing portion of our total sales in the near future. We intend to further leverage our advantages established by the GTP platform to support continuous sales contribution from the retail channels, for both of our existing and future products. We also aim to build our GTP platform into an academic and patient education platform where we could engage with patients and doctors to raise awareness of the treatment of relevant diseases in an interactive setting.

In addition, we intend to further invest in our GTP platform by introducing the Internet Hospital Model through collaboration with third-party service providers, aiming to further expand patient access and allow for easier reach to prescription. Through the Internet Hospital Model, patients are able to complete the online consultation with doctors, get e-prescriptions from the doctors, get nearby pharmacies to fill the prescriptions and deliver to doors, all without the need to leave home. We are in discussion with business partners to implement the Internet Hospital Model in Suzhou, and we plan to expand such model to more cities. With introduction of this innovative model, we allow easier access to our products with safe and well-established consultation and prescription procedures in place. We anticipate further increase of retail sales brought by such efficient channel.

To facilitate our cooperation with the Internet Hospital Model, we also intend to expand our coverage of the pharmacies in China. For instance, we intend to deepen our collaboration with Sinopharm by engaging its extensive retail network for the prescription and promotion of our products in the Internet Hospital Model. The coverage of pharmacies solves the last-mile problem by arranging short-distance delivery and pick-up services benefiting both our retail partners and us.

We intend to further enhance affordability of our products by collaborating with commercial insurance companies to increase the insurance coverage of our products. We actively pursue the

opportunities for our products to be included in the coverage of commercial medical insurance products to meet the increasing demand of patients.

Our clinical development model utilizes our existing strengths in late-stage candidate development and also closely collaborates with renowned CROs for early-stage candidate development. We select our CRO partners on a project-by-project basis, and our selections are mainly based on their expertise and quality standards. By combining the development strengths of both our own in-house clinical operations team and our CRO partners, we are able to keep a lean team for study design and effective operation management, and to achieve our development goals with relatively low costs.

We will further invest in our business development team, clinical development team and regulatory affairs team which collaborate closely to ensure smooth introduction of promising candidates and timely launches of the products:

- We intend to further support our business development team to select candidates with great commercial potential in the therapeutic areas we focus on.
- We intend to further invest in our clinical operations team, building up its multi-dimensional functionality, including development strategy planning, data management and statistics to enhance its capabilities of managing large-scale local clinical trials. We target to build a well-rounded clinical operations team which could assist the business development team in assessing and reviewing new candidate development opportunities to maximize our candidates' commercial potential with accelerated development plans. We intend to strengthen our product development capabilities for late-stage candidate development by expanding our clinical operations team to manage and execute clinical trials more efficiently, and for early-stage candidate development by collaboration with clinical trial partners.
- We also intend to enhance our regulatory affairs team's capabilities in accelerating the timeline from sourcing of candidates to regulatory approval and market launch. Through in-depth knowledge of China's pharmaceutical regulations and petition for successful fast-track designations, our regulatory affairs team sets and completes accelerated registration strategies.

Commit to development of talent and enhancement of our operational infrastructure to support our future expansion

We intend to further allocate resources to recruit, train and retain high-calibre talents which we believe are crucial to the success of our business and the implementation of our strategies. We intend to establish effective incentive mechanisms, including employee stock ownership plans to attract and retain top talents. We focus on bringing in the talents that serve the different needs of our functional teams. We will invest in our training programs to help our employees develop their competency and skill sets required for carrying out their responsibilities, so that they can excel in the areas they focus on. With continuous focus on our talents, we believe we will maintain a fighting force to help us navigate through the market opportunities and challenges.

We will also further invest in our financial, IT, management and operation systems, to maximize the utilization of our internal resources and integrate the external resources. We plan to continuously upgrade our internal systems to achieve seamless internal integration, in order to monitor full and transparent sales and marketing activities to ensure compliance with relevant rules and regulations, and also to enable more effective allocation of resources and increase operational efficiency. We also intend to further invest in our GTP platform and other digital technologies to enhance our cross-functional collaboration. With our active development and investment in technologies and online platforms, we aim to achieve operational efficiency by reaching more stakeholders, customers and patients with lower costs.

OUR BUSINESS DIVISIONS

We are a biopharmaceutical company with an integrated platform for product development and commercialization, with our business operations strategically covering two divisions in the pharmaceutical industry value chain:

Sales of our proprietary and in-licensed pharmaceutical products:

We engage in the sales of our proprietary pharmaceutical product, Zadaxin, and our in-licensed pharmaceutical products, such as Angiomax and Zometa.

For our proprietary pharmaceutical product, we hold the global proprietary rights and intellectual property rights for Zadaxin. See "— Products and Services — Our Proprietary Product." We outsource the production of Zadaxin to an industry-leading and highly reputable CMO. See "— Production and Quality Control — Production through CMOs." We primarily sell Zadaxin in China due to the large number of patients in China with chronic hepatitis B, which is one of the indications of Zadaxin. In 2017, 2018 and 2019, and the nine months ended September 30, 2019 and 2020, the proportion of our Zadaxin sales in China, among our total sales of Zadaxin in terms of revenue, was 93.5%, 91.2%, 92.9%, 94.0% and 93.8%, respectively; and the proportion of our Zadaxin sales overseas, among our total sales of Zadaxin in terms of revenue, was 6.5%, 8.8%, 7.1%, 6.0% and 6.2%, respectively. We derive revenue from sales of Zadaxin to our importer, Sinopharm, which further distributes such product to hospitals and pharmacies in China. See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China" and "— Sales, Marketing and Distribution — Distribution in China — Distribution Network for our Proprietary and In-licensed Products." In overseas markets, we sell Zadaxin through our local business partners.

For our in-licensed pharmaceutical products, we are granted by our business partners the exclusive rights to commercialize such products in China and selected products in certain other countries. For Zometa, we own or are authorized to use the intellectual property rights in China; for Angiomax, we are authorized to use the intellectual property rights in China. See — Products and Services — Our In-licensed Products." We engage in product development for our in-licensed products in accordance with the commercialization arrangements with our business partners. See "—

Product Development." Our in-licensed products include not only marketed products such as Angiomax and Zometa, but also a diversified pipeline of potential drug candidates in different stages of development. See "— Product Development — Products under Development." We also outsource the production of our in-licensed pharmaceutical products to industry-leading, highly reputable CMOs. See "— Production and Quality Control — Production through CMOs." We derive revenue from sales of such products to our distributors. See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China" and "— Sales, Marketing and Distribution — Distribution in China — Distribution Network for our Proprietary and In-licensed Products."

Sales of promotion products for business partners:

We also sell promotion products in Mainland China for our business partners, Pfizer and Baxter. See "— Products and Services — Our Sales of Promotion Products for Business Partners." For our sales of promotion products for business partners, we derive revenue from the sales of such promotion products to distributors. See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China" and "— Sales, Marketing and Distribution — Distribution in China — Distribution Network for Promotion Products for Business Partners."

The table below sets forth our revenue by business divisions for the periods indicated:

	For the year ended December 31,						Nine months ended September 30,			
	2017		2018		2019		2019		2020	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
							(unaudited)			
Product sales										
Zadaxin (日达仙)	1,112,610	91.7	1,168,816	83.0	1,349,309	79.0	1,035,089	80.2	1,326,337	83.7
Promotion products for our business partners	56,687	4.7	208,720	14.8	314,333	18.4	222,632	17.2	250,892	15.8
DC Bead[(1)]	15,846	1.3	28,680	2.0	44,426	2.6	33,050	2.6	6,944	0.5
Promotion service revenue	27,823	2.3	2,653	0.2	—	—	—	—	—	—
Total	**1,212,966**	**100.0**	**1,408,869**	**100.0**	**1,708,068**	**100.0**	**1,290,771**	**100.0**	**1,584,173**	**100.0**

Note: (1) We also generated revenue from the sales of our in-licensed product DC Bead during the Track Record Period, and the sales of DC Bead was discontinued on April 30, 2020.

PRODUCTS AND SERVICES

Our marketed products include our proprietary product, Zadaxin, and our in-licensed products, Angiomax and Zometa. In addition, we also sell promotion products for our business partners, Pfizer and Baxter. The chart below sets forth information relating to our marketed products as of the Latest Practicable Date:

Marketed Products

	Product Name	Mechanism of Action	Indication(s)	Originator / Partner	Commercial Rights
Proprietary	Zadaxin® (thymalfasin)	Immunomodulator of thymalfasin	Cancers / infectious diseases	–	Proprietary asset
License-in	Zometa® (zoledronic acid)	Osteoclast-mediated bone resorption inhibitor	Bone metastases from solid tumors	Novartis (Switzerland)	Permanent right to commercialize in Mainland China IP acquired or licensed
Promotion products for business partners	Farlutal (Medroxyprogesterone Acetate)	Gonadotropin inhibitor	Cancers	Pfizer (USA)	Promotion services and distribution through 2022 for renewal
	Methotrexate	DHFR inhibitor Nuclear estrogen receptors and DNA synthesis reducer	Acute leukemia / cancers		
	Estracyt (Estramustine Phosphate)	DNA alkylator	Hormone resistant advanced prostate cancer		
	Holoxan (Ifosfamide)	DNA and protein synthesis inhibitor	Cancers	Baxter (USA)	Promotion services and distribution through 2022 for renewal
	Mesna (Sodium-2-mercaptoethane Sulfonate)	Organosulfur compound used as an adjuvant in cancer chemotherapy to detoxify urotoxic metabolites	Urotoxicity		
	Endoxan (Cyclophosphamide)	Protein synthesis inhibitor through cross-linking of DNA and RNA	Cancers		

Abbreviations: DHFR = Dihydrofolate Reductase; DNA = Deoxyribonucleic Acid; PCI = Percutaneous Coronary Intervention; RNA = Ribonucleic Acid

Notes:

(1) As of the Latest Practicable Date, Zometa was sold through the existing distribution network by Novartis in several provinces in China, and we recognized other income from Zometa through our licensing arrangement with Novartis to receive profit transferred from Novartis for the sales of Zometa. We also started recognizing revenue from our sales of Zometa since December 2020 as we began distributing Zometa in certain provinces in China. In January 2021, we completed the transfer of IDL for Zometa, and became the MAH of Zometa in the PRC.

(2) As of the Latest Practicable Date, all of these marketed products were covered by the centralized tender process, and none of these marketed products was covered by the volume-based procurement. See "Regulatory Overview — Drug Purchase by Hospitals."

(3) As of the Latest Practicable Date, Holoxan, Mesna and Endoxan were listed in the National Essential Drug List. See "Regulatory Overview — National Essential Drug List."

Product to be Marketed

	Product Name	Mechanism of Action	Indication(s)	Originator / Partner	Commercial Rights
License-in	Angiomax® (bivalirudin)	Anticoagulant for PCI	Percutaneous transluminal coronary angioplasty Percutaneous coronary intervention	The Medicines Co. (USA)	Permanent right to commercialize in Mainland China IP licensed

Note:

(1) We entered into a Product Promotion Agreement with Huizheng on August 31, 2020, under which Huizheng was engaged for the promotion and distribution of our in-licensed product Angiomax in Mainland China. Angiomax is expected to be commercialized in the first quarter of 2021.

In addition, we also have a pipeline of product candidates. See "Product Development — Products under Development."

Our Proprietary Product

Zadaxin 日达仙

Zadaxin is our synthetic preparation of thymalfasin (胸腺法新), scientifically referred to as thymosin alpha 1 (胸腺肽α1) ("Tα1"), a thymic peptide which circulates in the blood naturally. Currently, Zadaxin is approved for treatment of chronic hepatitis B and vaccine enhancement in patients with impaired immunity. Besides the official indications, in the treatment guidelines issued by the NHC and professional associations including the Chinese Medical Association and the CSCO, Zadaxin is also listed for the treatments of sepsis (in 2014), pancreatic cancer (in 2019), liver cancer (in 2017, 2018 and 2019) and COVID-19 (in 2020). Based on the feedback from hospitals and doctors, through our ongoing communication with them regarding the application of and the effectiveness of Zadaxin for its indications and clinical adoptions, as well as through prescription data provided by third-party data vendors, we believe that sales of Zadaxin to patients with chronic hepatitis B and cancers, in comparison with sales to patients with other indications and clinical adoptions of Zadaxin, were relatively more important to our results of operation during the Track Record Period.

Mechanism of Action

Tα1, initially selected for its activity in restoring immune function to thymectomized mice, was the first peptide to be isolated from thymic tissue. Synthesized Tα1 is chemically identical in amino acid sequence to Tα1 isolated from thymosin fraction-5 (TF-5), an extract from the thymus gland. Tα1 is an N-terminal acetylated acidic peptide of 28 amino acids with a molecular weight of 3108 Da. Circulating Tα1 is the amino terminal proteolytic cleavage product of the chromatin-remodeling protein prothymosin and is derived from cleavage of prothymosin by the lysosomal asparaginyl endopeptidase legumain. Tα1 is a highly conserved peptide and is therefore of biological significance, because its amino acid sequence is homologous in bovine, porcine, ovine, and human species, and similar peptides have even been found in crustaceans. Endogenous Tα1 serum levels measured in healthy adults by immunoassay are in the 0.1 to 1.0 ng/mL range, although the circulating concentration tends to be lower in diseased individuals and higher during pregnancy. While the highest concentrations of Tα1 are found in the thymus, the peptide has also been found in spleen, lung, kidney, brain, blood, and a number of other tissues. A chemically synthesized version of Tα1 shows activity similar to the native peptide.

Investigation of the mechanism of action of Tα1 at the cellular level has implicated a number of intracellular cell-signaling pathways leading to stimulation of the immune system. These immunological effects can explain Tα1's effectiveness in treatment of indications where a stimulated or enhanced immune response is desirable, including acute infections, chronic viral infections such as hepatitis B and C, cancer, and enhancement of vaccines.

Tα1 has been shown to be a TLR9 agonist. The TLRs are a family of proteins that mediate innate immunity; stimulation of one or more TLRs by a TLR agonist can enhance the adaptive

immune response which is critical for fighting viral, bacterial, and fungal infections and cancers, as well as stimulation of humoral immunity for vaccine effectiveness. Tα1 affects both myeloid and plasmacytoid dendritic cells (DCs), the professional antigen-presenting cells, leading to activation and stimulation of signaling pathways and initiation of production of immune-related cytokines that fight infections. Tα1 also affects precursor T cells, leading to an increase in the number of activated T helper (Th) cells (CD4 T cells) and a shift towards the Th1 subclass. This shift leads to increased expression of Th1-type cytokines such as IL-2, and IFN-alpha. The activated DCs and Th1 cells then act in concert to kill bacterial, fungal, or viral infections or tumor cells and lead to the stimulation of differentiation of specific B cells to antibody-producing plasma cells and an improvement in response to vaccines by stimulation of antibody production. Tα1's effects on TLR9 lead to stimulation of the NFkappaB and p38 MAPK pathways, both of which play critical roles in the maturation of DCs and in the antigen presentation by DCs. Tα1 leads to increased expression of the thymopoetic cytokines IFN-α, IL-7, and IL-15.

Tα1 can reduce apoptosis of immune cells, as shown in mouse and human thymocytes, and stem cell expansion or differentiation in immunosuppressed mice. Tα1 treatment also leads to an increase in intracellular glutathione (GSH), which is important for anti-viral effects, and to direct inhibition of the *in vitro* growth of certain cancer cells.

In addition to its effects on DCs and T helper cells, Tα1 also stimulates innate immunity, including NK cells and macrophages, additionally supporting its anti-viral and anti-cancer activities. NK cell activity has been shown to be increased by Tα1 in a variety of model systems, including infections (mice with HSV or influenza), as well as cancers in mice and rats and polymorphonuclear blood cells (PMBCs) from human patients. In human monocyte-derived macrophages, Tα1 helps implement pathogen internalization and phagocytosis.

Importantly, it has also been shown that Tα1 stimulates activity of indoleamine-2,3-dioxygenase (IDO) in plasmacytoid dendritic cells.2,3,63 Stimulation of IDO leads to an increase in FoxP3+ IL-10 producing regulatory T cells, and this increase leads to feedback inhibition of cytokine production, hence dampening immune response to prevent a pro-inflammatory cytokine storm.

It is clear from the mechanism of action that Tα1 could be useful in many different clinical adoptions in which an improvement in the immune system would be beneficial.

Indications and Clinical Adoptions

I Infectious Diseases

A number of *in vivo* and *in vitro* studies have suggested that Tα1 is useful in the treatment of infectious diseases, mainly hepatitis B, COVID-19 and sepsis.

(a) Hepatitis B

Chronic infections resulting from infection with HBV, HCV and HIV are considered hallmarks of immune suppression, resulting from the myriad pathways of immune system evasion that the viruses have evolved. Although most adults are able to clear the acute infection, those individuals with impaired cellular immune mechanisms, including the young, do not effectively clear HBV-infected hepatocytes and chronic infection results, and therefore correlated with a greatly increased risk for developing cirrhosis, liver failure, and HCC. Interest in Tα1 for treatment of CHB was based on its immunomodulating effects, primarily the improved maturation of lymphocytes and augmentation of T cell function. Clinical studies with Tα1 have resulted in disease remission in 26% to 41% of the patients treated. An independent meta-analysis of 435 patients entered into randomized controlled studies of Tα1 monotherapy for CHB demonstrated a statistically significant benefit in favor of Tα1 therapy, inducing a sustained virological response. A study supported by the National Science and Technology Major Project (2013ZX10002004) showed combination therapy of entecavir with Tα-1 has a tendency to inhibit the development of HCC in HBV-related compensated cirrhosis. (See Trial 1.1 below for details.) More recently, a study completed in 2019 demonstrated Tα-1 significantly improves the 90-day survival rate due to decreasing the incidence of complications in HBV-related acute-on-chronic liver failure (ACLF) patients. (See Trial 1.2 below for details.) The ongoing study in this area to evaluate the efficacy and safety of entecavir combined with Tα-1 in the treatment of HBeAg positive patients is promising. (See Trial 1.3 below for details.)

The table below summarizes details of some of the clinical trials or studies related to Zadaxin's use in the treatment of hepatitis B:

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
1.1	Combination of entecavir with thymosin alpha-1 in HBV-related compensated cirrhosis: a prospective multi-center randomized open-label study (Registration number: NCT 01943617)	Completed	2013 - 2016	The National Science and Technology Major Project (2013ZX10002004) (sponsored by the Company)	China	During the follow-up, 35 patients in the entecavir ("ETV") group reported serious adverse events ("SAE"). 26 of them were reported with primary endpoints, and eight were in the hospital for other problems. In the combination group, 26 patients were reported with primary endpoints and one patient was reported with myeloproliferative neoplasms. No events were	The cumulative incidence of liver decompensation, HCC, or death were similar between two groups. During the Tα1 combination treatment, the HCC incidence was 1.7% in combination group and 2.1% in ETV group, without new HCC cases developed during week 39 to week 77 in combination group. The virologic response, serologic

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
						considered to be relevant to the study of drugs. Both the drugs were well-tolerated.	response, biochemical response was similar between two groups at week 104. There was no significant difference between two groups in endpoint events, while combination therapy with Tα1 has a tendency to inhibit the development of HCC.
1.2	Rescue 2017010109 (Registration number: NCT 03082885)	Completed	April 2017 - July 2019	Investigators at the Third Affiliated Hospital of Sun Yat-sen University (sponsored by the Company)	China	The incidences of new infection and hepatic encephalopathy in the Tα1 group were much lower than those in the Standard Medical Therapy ("SMT") group (25.0% vs 58.6%, P<0.001; 8.9% vs 24.1%, P= 0.029, respectively). Mortality from severe infection in the SMT group was higher than in the Tα1 group (24.1% vs 8.9%, P=0.029).	The 90-day cumulated survival rate of the Tα1 group was 75.0% (95% confidence interval 63.2–86.8%) versus 53.4% (95% confidence interval 39.7–67.1%) for the SMT group (P=0.030).
1.3	KY2015-294	Ongoing	Started in September 2017	Investigators at Hua Shan Hospital of Fudan University. (sponsored by the Company)	China	NA(1)	NA(2)

Notes:

(1) No specific clinical results directly addressing safety.

(2) No specific clinical results directly addressing efficacy.

(b) COVID-19

Zadaxin has the potential to treat COVID-19 by enhancing the immunity of the patients and protecting the immune systems of the patients from being attacked by the virus, so that the immune systems can defend the patients against the virus. Tα1 has been investigated in clinical studies for inflammatory diseases, including bone marrow transplant-related infections, chronic obstructive pulmonary disease (COPD), acute respiratory distress syndrome (ARDS), and severe acute respiratory syndrome (SARS). Many studies reported that lymphocytopenia and T cell exhaustion is notable in acute COVID-19 patients, especially in aged and severe cases. Tα1 had been used in the treatment of viral infections as an immune response modifier for many years. However, clinical benefits and mechanism of Tα1 supplement to COVID-19 are still being explored. During the COVID-19 pandemic, most COVID-19 cases displayed severe lymphocytopenia, especially in aged and severe cases. Tα1 can effectively increase T cell numbers, support the differentiation and maturation of T Cells, and reduce cell apoptosis. To enhance immunity, the medical support team members from all over the country got Tα1 injection before being deployed to Hubei Province, and no infectious cases were reported till now, suggesting Tα1 might have the potential to prevent SARS-CoV-2 infection. A retrospective study was performed to evaluate the efficacy and safety of Tα1 treatment in severe COVID-19. The study indicated Tα1 supplement significantly reduced mortality of severe COVID-19 patients. Tα1 reverses T cell exhaustion and recovers immune reconstitution through promoting thymus output during SARS-CoV-2 infection. (See Trial 2.1 below for details.) Another study showing Tα1 protected T cells from excessive activation in severe COVID-19 was accepted by *Cell Research* in August 2020. (See Trial 2.2 below for details.) Zadaxin had been used by both patients infected by COVID-19 and uninfected population as a preventative measure for COVID-19.

The table below summarizes details of some of the clinical trials or studies related to Zadaxin's use in the treatment of COVID-19:

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
2.1	Thymosin alpha 1 reduces the mortality of severe coronavirus 2019 by restoration of lymphocytopenia and reversion of exhausted T cells (published in *Clinical Infectious Diseases* in 2020[1])	Completed	December 2019 - March 2020	Investigators at the General Hospital of the Central Theatre Command and Wuhan Pulmonary Hospital	China	NA[(3)]	The study indicated Tα1 supplement significantly reduced mortality of severe COVID-19 patients. Tα1 reverses T cell exhaustion and recovers immune reconstitution through promoting thymus output during SARS-CoV-2 infection.
2.2	Dysregulated adaptive immune response contributes to severe COVID-19 (published in *Cell Research* in 2020[2])	Completed	Completed in 2020	Investigators at State Key Laboratory of Oncology in South China and Collaborative Innovation Center for Cancer Medicine of Sun Yat-sen University	China	NA[(3)]	Compared to the non-treated patients, the lymphocyte counts of the treated patients were significantly increased after one week of Tα1 treatment.

Notes:

(1) Yueping Liu, Yue Pan, Zhenhong Hu, Ming Wu, Chenhui Wang, Zeqing Feng, Congzheng Mao, Yingjun Tan, Ying Liu, Li Chen, Min Li, Gang Wang, Zilin Yuan, Bo Diao, Yuzhang Wu, Yongwen Chen, Thymosin Alpha 1 Reduces the Mortality of Severe Coronavirus 2019 by Restoration of Lymphocytopenia and Reversion of Exhausted T Cells, Clinical Infectious Diseases, ciaa630, https://doi.org/10.1093/cid/ciaa630

(2) Yu, K., He, J., Wu, Y. et al. Dysregulated adaptive immune response contributes to severe COVID-19. Cell Res 30, 814-816 (2020). https://doi.org/10.1038/s41422-020-0391-9

(3) No specific clinical results directly addressing safety.

(c) Sepsis

Tα1 has shown benefit in treatment of sepsis in several mouse models, both as a monotherapy and in combination with dexamethasone or anti-PD-1 antibodies. Tα1 has also been demonstrated to protect against a variety of specific acute infections in immuno-suppressed animals, including Serratia marcescens, Pseudomonas aeruginosa, Listeria monocytogenes, and Candida albicans. A large, prospective, multicenter, single-blind, randomized, placebo-controlled trial (ETASS) with 361 patients was conducted to further evaluate the efficacy and safety of Tα1 for the treatment of severe sepsis. The 28-day mortality from any cause was 26% in the Tα1-treated group, which was much lower than that in control group. (See Trial 3.1 below for details.) To further confirm the outcome of the ETASS study, a larger scale prospective, multicenter, double-blind, randomized, placebo-controlled trial with 1,106 patients is ongoing. (See Trial 3.2 below for details.)

The table below summarizes details of some of the clinical trials or studies related to Zadaxin's use in the treatment of sepsis:

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
3.1	ETASS trial (Registration number: NCT00711620) (published in *Critical Care* in 2013[1])	Completed	May 2008 - December 2010	Investigators at the First Affiliated Hospital of Sun Yat-sen University	China	No Tα1-related severe adverse event ("SAE") was reported and no treatment was discontinued due to intolerance or adverse events.	The 28-day mortality from any cause was 26% in the Tα1-treated group, which was lower than that in control group.
3.2	Sepsis ZDX-2015-11: multi-center, randomized, double-blind, placebo controlled study of Tα1 in ICU sepsis patients (Registration number NCT02867267)	Ongoing.	Started in August 2016	Investigators at the First Affiliated Hospital of Sun Yat-sen University (sponsored by the Company)	China	Key indicators to be used include adverse events, vital signs and laboratory indices.	Key indicators to be used include 28-day all-cause mortality.

Note:

(1) Wu, J., Zhou, L., Liu, J. et al. The efficacy of thymosin alpha 1 for severe sepsis (ETASS): a multicenter, single-blind, randomized and controlled trial. Crit Care 17, R8 (2013). https://doi.org/10.1186/cc11932

Tα1 has been listed in a series of treatment guidelines issued by professional associations for the treatment of infectious diseases, including: (i) the "Guidelines for the Treatment of Severe Sepsis/Septic Shock in China (2014 Edition)" issued by the Chinese Society of Critical Care Medicine, (ii) the "APASL Asia-Pacific Clinical Practice Guidelines: Management of Hepatitis B (2015 Updated Version)" issued by Asian Pacific Association for the Study of the Liver and the "2016 Clinical Practice Guidelines for China's Emergency Septic Shock" issued by the Chinese Medical Association of Emergency Physicians and (iii) the "Guide to Diagnosis and Treatment of Liver Failure (2018 Edition)" issued by the Chinese Society of Infectious Diseases and Chinese Society of Hepatology. In addition, Tα1, including Zadaxin as well as its generic drug competitors, has been listed for the treatment of severe and critical cases of COVID-19 in 2020, which was released by NHC and State Administration of Traditional Chinese Medicine.

II Cancers

Based on the immunostimulatory activities of thymosin, early clinical trials assessed the efficacy of Tα1 in patients with primary immunodeficiencies as well as in cancer patients. Tα1 is used in cancer patients to enhance the immune capabilities with two aims: combating the tumor more efficiently and preventing opportunistic infections. In addition, the use of Tα1 could counteract the immunosuppressive side effects associated with conventional chemotherapy and radiotherapy. Tα1 has been shown to have beneficial effects in several experimental models of cancer, improving immune parameters and increasing survival in many different model systems: DHD/K12 colon carcinoma, B-16 melanoma, non-small-cell lung cancer, Lewis lung carcinoma, and Friend erythroleukemia. Tα1 treatment has also been shown to prevent lung carcinogenesis in mice injected with a chemical carcinogen, and to decrease lung metastases in a mouse model of melanoma. In recent years, several studies have been performed on a variety of tumors (melanoma, hepatocellular carcinoma ("HCC") and non-small cell lung cancer) to assess the safety and efficacy of Tα1 in cancer therapy.

Besides its use in the prevention in chronic hepatitis B, Tα1 has also been used in therapeutic treatment of HCC. A recent report has retrospectively evaluated the use of Tα1 as adjuvant therapy in patients with primary HBV-related small HCC after liver resection. As compared to patients that received only liver resection, patients treated with Tα1 had higher overall survival and recurrence-free survival, together with a reduced neutrophil-to-lymphocyte ratio. (See Trial 4.1 below for details.) A large, prospective, multi-center, randomized controlled study to further confirm this finding had also been conducted in West China Hospital of Sichuan University. (See Trial 4.2 below for details.)

Based on these results and the reinforced notion that the combination of immunotherapy and chemotherapy may be beneficial in melanoma because of its immunogenicity, a Phase II,

multicenter, open, randomized, dose ranging study was performed to investigate the safety and efficacy of different doses of Tα1 in combination with dacarbazine and with or without IFNa in stage IV melanoma. This study confirmed that administration of Tα1 did not result in additional toxicity while increasing the efficacy of the treatment as evident from the higher clinical benefit rate and a trend toward improved overall survival (OS) and higher progression free survival (PFS) with any Tα1-containing regimen.

The mechanisms on the basis of these effects are unknown, but are likely to involve the immunomodulatory activities of Tα1. To further elucidate the benefit of treatment with Tα1, exploring monotherapy or combination treatment with anti-PD-1 antibody, a study was performed in several murine melanoma and sepsis nonclinical models. In the lung metastasis model, Tα1 treatment alone led to a 32% decrease in metastases ($p<0.05$). Additionally, combinations of Tα1 and an anti-PD-1 antibody led to significantly fewer metastases than the vehicle. This concept was substantiated by a Tα1 compassionate use program in which 31 patients with advanced-stage malignant melanoma were treated with Tα1 and dacarbazine and a clinical benefit rate of 41% was observed. The patients enrolled in the two studies were further analyzed in a long-term follow-up study and an encouraging OS was observed, indicating that a proportion of patients benefits for a long time from the treatment with Tα1. The study also analyzed possible interactions with immune checkpoint inhibitor. When the analysis was focused on patients that received ipilimumab in a second or subsequent line of therapy, the median OS was 38.4 months if Tα1 was administered before ipilimumab, compared to eight months with ipilimumab alone, irrespective of timing from last Tα1 treatment, Tα1 dosage or Tα1 cycles. These results point to a synergistic effect of a sequential Tα1 and ipilimumab regimen. (See Trial 4.3 below for details.) A more recent multicenter, randomized controlled study in China is ongoing to evaluate the efficacy and safety of Tα1 combined with PD-1 antibody and apatinib in advanced gastric cancer after second-line treatment. (See Trial 4.4 below for details.)

The table below summarizes details of some of the clinical trials or studies related to Zadaxin's use in the treatment of cancers:

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
4.1	Thymalfasin, a promising adjuvant therapy in small hepatocellular carcinoma after liver resection (published in *Medicine* in 2017[1])	Completed	February 2007 - February 2013	Investigators at West China Hospital of Sichuan University	China	NA[(3)]	As compared to patients that received only liver resection, patients treated with Tα1 had higher overall survival and recurrence free survival, together with a reduced neutrophil-tolymphocyte ratio.

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
4.2	Multi-center, randomized, controlled clinical trial to evaluate the efficacy and safety of adjuvant thymalfasin therapy in hepatitis B virus (HBV)-related hepatocellular carcinoma after curative resection (Registration number: ChiCTR1800014409)	Ongoing	Started in September 2017	Investigators at West China Hospital, Sichuan University (sponsored by the Company)	China	Key indicators to be used include adverse events, vital signs and laboratory indices.	Key indicators to be used include recurrence-free survival ("RFS") of the patient with adjuvant thymalfasin vs without adjuvant thymalfasin in hepatocellular carcinoma after curative resection.
4.3	Long-term follow up of metastatic melanoma patients treated with thymosin alpha-1: investigating immune checkpoints synergy (Registration number: NCT00911443) (published in *Expert Opinion on Biological Therapy* in 2018[2])	Completed	June 2004 - July 2017	Investigators at Center for Immuno-Oncology, University Hospital of Siena, Siena, Italy	Italy	NA[(3)]	Median OS at the data cut-off was 57.8 and 7.4 months in patients treated sequentially with anti-CTLA-4 imAbs or not, respectively. Moreover, pre-treatment with Tα1 in all (95) ipilimumab ("IPI") - evaluable patients confirmed a significant increase in long-term OS. Results obtained in long-term follow-up of 95 patients treated with IPI showed a statistically significant OS rate increase at 3, 4, and 5 years among patients receiving Tα1-IPI sequence versus patients treated with IPI and who had never received Tα1 (52.9% vs 16.9% p = 0.001), (41.2% vs 14.3% p = 0.01), and (41.2% vs 13.0% p = 0.006).

Trial No.	Clinical trial or study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
4.4	Efficacy and safety of thymosin α1 combined with PD-1 antibody and apatinib in advanced gastric cancer after second-line treatment: a multicenter, open, randomized, controlled trial (Registration number: ChiCTR1900025367)	Ongoing.	Started in May 2019	Investigators at the Shanghai East Hospital (co-sponsored by the Company)	China	Key indicators to be used include adverse events	Key indicators to be used include progression free survival and objective remission rate

Notes:

(1) He, Chao MD; Peng, Wei MD; Li, Chuan MD; Wen, Tian-Fu PhD* Thymalfasin, a promising adjuvant therapy in small hepatocellular carcinoma after liver resection, Medicine: April 2017 — Volume 96 — Issue 16 — p e6606 doi: 10.1097/MD.0000000000006606

(2) Danielli R, Cisternino F, Giannarelli D, Calabrò L, Camerini R, Savelli V, Bova G, Dragonetti R, Di Giacomo AM, Altomonte M, Maio M. Long-term follow up of metastatic melanoma patients treated with Thymosin alpha-1: investigating immune checkpoints synergy. Expert Opin Biol Ther. 2018 Jul;18(sup1):77-83. doi: 10.1080/14712598.2018.1494717.

(3) No specific clinical results directly addressing safety.

Tα1 has been listed in a series of treatment guidelines issued by professional associations for the treatment of cancer, including: (i) the "Guidelines for the Diagnosis and Treatment of Primary Liver Cancer (2017 Edition)" and the "Guidelines for the Diagnosis and Treatment of Primary Liver Cancer (2019 Edition)," both issued by the NHC, (ii) the "Guidelines for the Diagnosis and Treatment of Pancreatic Cancer (2019 Edition)" and the "Guidelines for the Diagnosis and Treatment of Primary Liver Cancer of CSCO (2018 Edition)," both issued by the CSCO, (iii) the "Chinese Lymphoma Diagnosis and Treatment Expert Consensus (2017 Edition)" issued by the Lymphoma Group of the Chinese Society of Oncology and (iv) the "Chinese Hepatocellular Carcinoma Transcatheter Arterial Chemoembolization (TACE) Clinical Practice Guidelines" issued by the Chinese College of Interventionalists.

III Vaccine Adjuvant

Tα1 has been shown to improve immune response to vaccines in several animal models, increasing the antibody response in old mice close to levels seen in young mice. The most recent study evaluated the addition of Tα1 as an enhancer of the immunogenicity of the 2009 H1N1 monovalent vaccine (Focetria®, Novartis) in adults with End-Stage Rental Disease on chronic dialysis. The results showed that patients who were treated with either dose of Tα1 achieved a marked and significant increase in their antibody titers compared to placebo. (See Trial 5.1 below for details.)

The table below summarizes details of a clinical study related to Zadaxin's use as vaccine adjuvant:

Trial No.	Clinical study conducted	Current status	Start and complete time	Responsible party	Geography	Safety: indicators and clinical data	Efficacy: indicators and clinical data
5.1	Thymosin alpha 1 enhances the immunogenicity of an adjuvated pandemic H1N1 influenza vaccine (FocetriaTM) in hemodialyzed patients (Registration number: NCT01031966) (published in *Vaccine* in 2012[1])	Completed	November 2009 - May 2010	Investigator at Padua Hospital	Italy	Key indicators used include adverse event recording, laboratory assays (hematology and chemistry), electrocardiogram, and assessment of vital signs.	The co-primary immunogenicity endpoints were the proportion of subjects with HI antibody titers of 1:40 or more, the proportion of subjects with either seroconversion or a significant increase in antibody titer, and the factor increase in geometric mean titer ("GMT") both in per-protocol and intention-to-treat populations.

Note:

(1) Carraro G, Naso A, Montomoli E, Gasparini R, Camerini R, Panatto D, Tineo MC, De Giorgi L, Piccirella S, Khadang B, Ceracchi M, De Rosa A. Thymosin-alpha 1 (Zadaxin) enhances the immunogenicity of an adjuvated pandemic H1N1v influenza vaccine (Focetria) in hemodialyzed patients: a pilot study. Vaccine. 2012 Feb 1;30(6):1170-80. doi: 10.1016/j.vaccine.2011.12.014.

Approvals and Intellectual Property

Zadaxin is approved in multiple jurisdictions, primarily in China but also in countries such as South Korea, Thailand, Argentina, Italy, Cambodia, Singapore and Indonesia. Zadaxin's approvals are principally for the treatment of Hepatitis B and as an immune system enhancer, with additional approvals in certain countries for the treatment of Hepatitis C, or as a chemotherapy immune enhancer for cancer patients with weakened immune systems. We developed Zadaxin in the early 1990s, and Zadaxin was approved by the NMPA for sales in China in 1996. Zadaxin was originally included in Part B of the NRDL since 1999, and was later removed based on decisions made by the regulators from Part B of the NRDL to be included in the work-related injury insurance catalog of the NRDL since February 2017. We continuously look for opportunities to expand the clinical adoptions of Zadaxin based on the ongoing double-blind randomized controlled studies in sepsis and real-world studies in oncology.

We are granted the rights to use five patents of Zadaxin in China by SciClone US, with expiry dates ranging from 2021 to 2030, covering areas such as method of reducing side effects of

chemotherapy in cancer patients, α thymosin peptides as cancer vaccine adjuvants, and α thymosin peptides as vaccine enhancers. We also hold 34 patents of Zadaxin in jurisdictions outside China, such as the United States, Italy, the United Kingdom, Japan, Germany and France.

Financial Performance, Market Potential and Effective Lifecycle Management

Zadaxin has consistently demonstrated proven market potential. In 2017, 2018 and 2019, our worldwide revenue from Zadaxin was RMB1,112.6 million, RMB1,168.8 million, and RMB1,349.3 million, respectively, representing a CAGR of 10.1% from 2017 to 2019. Such robust growth in revenue is sustained by both the fast growth of the thymalfasin market in China and Zadaxin's ability to continuously gain market share from the generic competition in recent years. According to Frost & Sullivan, the sales revenue of thymalfasin in China was approximately RMB2.4 billion in 2019, growing at a CAGR of 3.5% from 2015 to 2019; the sales revenue of thymalfasin in China is expected to further grow to approximately RMB4.6 billion in 2024, representing a CAGR of 13.9% from 2019 to 2024. According to Frost & Sullivan, in terms of sales revenue, Zadaxin accounted for 44.1% of market share in the thymalfasin market in China in 2015, and 57.5% of market share in the thymalfasin market in China in 2019. According to Frost & Sullivan, as the first and branded thymalfasin drug in China, Zadaxin has competitive edge over other thymalfasin drugs as it has strong brand recognition and product loyalty, based on its first-mover advantage.

Zadaxin's robust demand and our proven lifecycle management capabilities maintained stable growth of our revenue despite external market challenges, including changes in reimbursement policies, changes in provincial and municipal centralized tender processes, fluctuation in prices and concerns over adjuvant therapies. Such challenges may be attributable to different factors. For example, when determining the pharmaceutical products covered by the reimbursement policies, the PRC regulators may consider factors including pricing, national and local economy conditions, and prominent public demands for treatment of certain diseases, and some of these factors may be beyond our control. In addition, Zadaxin has faced, and will continue to face, competition from generic thymalfasin and other generic thymic hormone drugs in Mainland China, a market we expect to continue to focus on. See "Risk Factors — Risks Relating to Our Business and Industry — We rely on the sales of a limited number of proprietary product and promotion products for business partners, especially in Mainland China, which account for a substantial portion of our total revenue. If we are unable to maintain the sales volume, pricing levels and profit margins of such products due to factors such as competition or change in government regulations, our operations, revenue and profitability could be adversely affected" and "Risk Factors — Risks Relating to Our Business and Industry — We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors selling competing drugs such as substitute or generic drugs and new innovative drugs, which could subject us to the pressure of price reduction and adversely affect our operations, revenue and profitability."

Nevertheless, we are able to effectively extend Zadaxin's lifecycle by expanding into new clinical adoptions based on additional clinical evidence. Our lifecycle management efforts for Zadaxin resulted in its inclusion in additional treatment guidelines. For example, since the outbreak of COVID-19, Zadaxin had been listed for the treatment of severe and critical cases of COVID-19

according to the treatment guideline issued by the NHC and National Administration of Traditional Chinese Medicine, which evidences our success in effectively expanding the use of Zadaxin into new clinical adoptions. We also expand our field force to cover additional hospitals and areas and upgrade our digital marketing efforts and innovative patient-oriented programs to establish new business models. Based on the pre-clinical and clinical studies, we expect to expand new clinical indications in the next 3 to 5 years. We plan to gradually develop the application of Zadaxin in the treatment of acute pancreatitis, rheumatic immune diseases, bone marrow transplantation and tumor immunotherapy combination with immune checkpoint inhibitors especially with PD-1/PD-L1. In particular, as of the Latest Practicable Date, we had undertaken a broad range of clinical studies to expand Zadaxin's clinical adoptions in oncology, severe infection, vaccine adjuvant and other therapeutic areas. For details, please see "— Our Strategies — Continue to strengthen our marketed product portfolio through effective lifecycle management". As a result, notwithstanding the above-mentioned challenges, we believe that our continued efforts in expanding the clinical adoptions of Zadaxin place us in a better position to benefit from growing public awareness of Zadaxin's mechanism and benefits. We also intend to implement effective sales, marketing and commercialization strategies to ensure that our lifecycle management efforts on Zadaxin are transformed into solid financial returns. See — "Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China."

Our In-licensed Products

Our in-licensed products include Angiomax and Zometa. Angiomax is indicated for use as an anticoagulant for use in patients undergoing percutaneous coronary intervention including patients with heparin-induced thrombocytopenia and thrombosis syndrome. Zometa is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, and hypercalcemia of malignancy.

Zometa 择泰

Zometa (generic name: zoledronic acid, 4mg/5ml concentrate for solution) is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, and hypercalcemia of malignancy. Zometa can be incorporated into bones and selectively inhibit osteoclast-mediated bone resorption, which inhibits increased osteoclastic activity and skeletal calcium release induced by tumors. Thus Zometa decreases serum calcium and phosphorus and increases urinary calcium and phosphorus excretion in patients with hypercalcemia of malignancy.

In China, Zometa was approved in 2004 and promoted by Novartis until early 2020. Zometa was included in the NRDL since 2009.

Before the completion of the IDL transfer, Novartis remained as the MAH of Zometa in the PRC, and we recognized the profit transferred from Novartis during the IDL transfer period as other income. We also started recognizing revenue from our sales of Zometa since December 2020 as we began distributing Zometa in certain provinces in China. In January 2021, we completed the transfer of IDL for Zometa, and became the MAH of Zometa in the PRC.

According to Frost & Sullivan, the market of bone metastases drugs in China, in terms of sales revenue, amounted to RMB1.3 billion in 2019, representing a CAGR of 2.4% from 2015 to 2019. The market is estimated to grow at a CAGR of 19.1% from 2019 to 2024 and to reach RMB3.1 billion in 2024, and is estimated to further grow at a CAGR of 20.5% from 2024 to 2030 and to reach RMB9.5 billion in 2030. The sales revenue of Zometa in China in 2019 was RMB205.7 million, ranked third in China's bone metastases market, with a market share of 15.9%. According to Frost & Sullivan, as a third-generation bisphosphonate, zoledronic acid (Zometa) has the highest relative potency compared to the first- and second-generation bisphosphonate drug, with more selectivity for inhibition of bone resorption.

Under the Asset Purchase Agreement, the License Agreement, the Supply Agreement, the Trademark Transfer Agreement and the Domain Name Assignment Agreement, each between us and Novartis signed in February 2020, Novartis transfers to us certain marketing authorization, domain name, trademark, other intellectual properties and third-party agreements related to Zometa. Salient terms of such agreements are listed below:

- **Nature of Rights**: Novartis transfers to us certain marketing authorizations, intellectual properties and third party agreements related to Zometa product, and grants us exclusive, perpetual, irrevocable, royalty-free, fully paid-up license to market, sell, use and commercialize Zometa in Mainland China and to manufacture Zometa in any country of the world for use in Mainland China.
- **Non-Compete**: For a period of three years, Novartis shall not commercialize a competing product in Mainland China or grant any third party rights to commercialize competing products in Mainland China.
- **IP Arrangements**: Novartis transfers to us certain rights in relation to trademarks and domain names.
- **Other Rights and Obligations**: We grant Novartis a non-exclusive, royalty-free, fully paid-up, perpetual license, and a right to use and reference the market authorizations to exercise Novartis' rights and to perform its obligations under the agreement, and to comply with relevant laws.
- **Supply**: Initially, Novartis shall manufacture, supply, distribute and/or commercialize Zometa in Mainland China. We shall obtain approvals necessary from the regulatory authorities to manufacture Zometa independent from Novartis, and shall subsequently, under the assistance of Novartis, establish manufacturing and supply relationship with the CMO for Zometa.
- **Payment**: We shall pay Novartis a non-refundable, non-creditable upfront payment in the low eight figures in US dollars, and milestone payments in the low to mid seven figures in US dollars conditional on achievement of certain milestone events. We shall also pay Novartis a royalty fee as a percentage of low double digits on the net sales of Zometa.

Angiomax 安其思

Angiomax (bivalirudin) is indicated for use as anticoagulant for use in patients undergoing percutaneous coronary intervention ("PCI") including patients with heparin-induced

thrombocytopenia and thrombosis syndrome. Angiomax directly inhibits thrombin by specifically binding both to the catalytic site and to the anion-binding exosite of circulating and clot-bound thrombin. Thrombin is a serine proteinase that plays a central role in the thrombotic process, acting to cleave fibrinogen into fibrin monomers and to activate Factor XIII to Factor XIIIa, allowing fibrin to develop a covalently cross-linked framework which stabilizes the thrombus; thrombin can also activate Factors V and VIII, promoting further thrombin generation, and activate platelets, stimulating aggregation and granule release. The binding of Angiomax to thrombin is reversible as thrombin slowly cleaves the bivalirudin-Arg3-Pro4 bond, resulting in recovery of thrombin active site functions.

In China, Angiomax was approved by the NMPA for sales in China in 2019. Since its approval, we have been working on its IDL transfer from The Medicines Company as well as the distributor engagement before its commercialization. As of the Latest Practicable Date, Angiomax was not included in the NRDL. Our Group is currently the MAH of Angiomax in the PRC.

We entered into a Product Promotion Agreement with Huizheng on August 31, 2020, under which Huizheng was engaged for the promotion and distribution of our in-licensed product Angiomax in Mainland China. Since our own sales and distribution network under SciClone Jiangsu currently does not have specialized distribution capacity for pharmaceutical products treating cardiovascular diseases, we engage Huizheng for the distribution of Angiomax as it can provide a broad distribution coverage for pharmaceutical products treating cardiovascular diseases. According to Frost & Sullivan, due to factors such as aging population, increasing number of patients with coronary disease, and improving accessibility to qualified healthcare institutions, the PCI procedure volume increased rapidly from approximately 567,600 in 2015 to approximately 1,064,000 in 2019, representing a CAGR of 17.0%, and is expected to further grow to approximately 1,967,500 in 2024, representing a CAGR of 13.1%. According to Frost & Sullivan, the expected further growth momentum of PCI anticoagulant is well proven by the large gap of PCI procedure volume in China and other developed countries, indicating significant growth potential for Angiomax.

Moreover, according to Frost & Sullivan, compared with other three types of anticoagulants for PCI, bivalirudin demonstrates several advantages: First, bivalirudin monotherapy significantly reduces major bleeding while providing similar ischemic protection and improves net clinical outcome; second, unlike unfractionated heparin or enoxaparin, bivalirudin does not inflict platelet activation; moreover, bivalirudin's combination with prothrombin is reversible.

Under the License Agreement between us and The Medicines Company signed in December 2014, as amended in November 2015, July 2019, and April 2020, with an indefinite term, we own IDL transferred from The Medicines Company and have the exclusive right to commercialize Angiomax in Mainland China. Salient terms of such agreements are listed below:

- **Nature of Rights**: The Medicines Company assigns us all right, title and interest in, to and under the IDL assets, the exclusive right in Mainland China, to develop and commercialize Angiomax, including but not limited to activities concerning using, importing, marketing, promoting, storing, handling, distributing, seeking hospital listing or selling of Angiomax.

- **Non-Compete**: We shall not develop, manufacture or commercialize any directly competing product in Mainland China, during the term of the agreement and within five years following the termination of the agreement.
- **IP Arrangements**: The Medicines Company grants us an exclusive, non-sublicensable license (except otherwise permitted by the agreement) to sell, import, distribute and commercialize the product under The Medicines Company's IP rights and trademark in Mainland China, and a non-exclusive, fully-paid-up, royalty-free, non-sublicensable worldwide license to make and manufacture Angiomax.
- **Other Rights and Obligations**: We shall exercise commercially reasonable efforts to commercialize the products, including obtaining regulatory approvals. We may appoint third party distributors for the commercialization of the product. We shall be the applicant and registrant for the IDL and shall use commercially reasonable efforts to maintain such IDL.
- **Supply**: We shall procure the supply of the product in Mainland China, with reasonable assistance from The Medicines Company to enter definitive agreements with CMOs for the manufacturing and supply of the product API, and the manufacturing and supply of the finished product. Before we enter into such definitive agreement, The Medicines Company shall supply Angiomax to us.
- **Payment**: We shall pay The Medicines Company a one-time, non-refundable, non-creditable upfront payment in the low eight figures in US dollars, and milestone payments in the mid seven figures in US dollars conditional on achievement of certain milestone events.

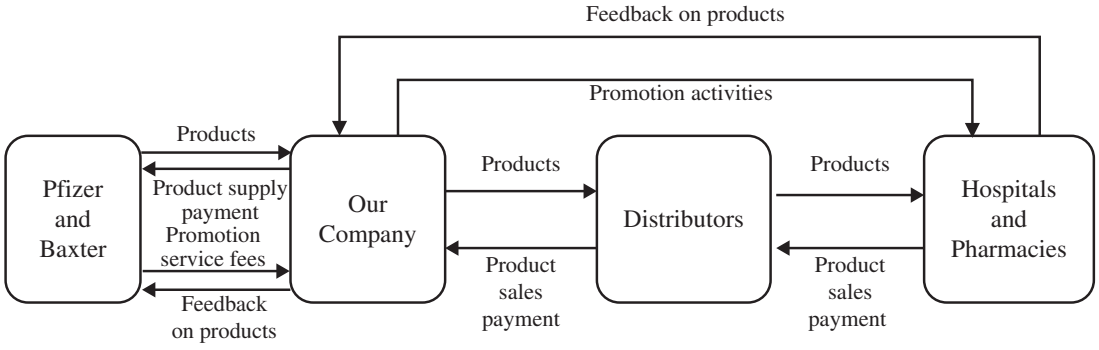
Our Sales of Promotion Products for Business Partners

We also engage in the sales of promotion drug products in China for our business partners, such as Pfizer and Baxter. For the promotion products we sell for our business partners, our business partners supply us with such promotion products, which are imported and distributed through SciClone Jiangsu. We engage in marketing and promotion activities for such promotion products and sell such promotion products to our distributors through the distribution network we manage. Currently, we have been granted rights to promote and sell six products in China. As a long-term and preferred partner for Pfizer and Baxter, we have delivered sustainable performance and gained market share from generic competition.

For the promotion products we sell for our business partners, we actively engage in sales and marketing activities to strengthen the products' recognition among doctors through academic marketing and promotional activities. Our marketing and promotional activities include participation in and sponsorship for academic events (such as health industry conferences, medical symposia, and educational seminars), discussion with doctors through teleconferences, demonstration of publicity videos and organization for promotional events for the products. To enhance the results, we typically provide at the marketing activities printed publicity documents, academic journal articles, drug samples, and other materials provided by our partners. See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China." Our distribution

services are conducted through SciClone Jiangsu together with a nationwide distribution network. See "— Sales, Marketing and Distribution — Distribution — Distribution Network for Promotion Products for Business Partners." For our sales of promotion products for business partners, we derive revenue from sales of such promoted products to distributors.

The following diagram illustrates the key parties and processes involved in our sales of promotion products for business partners:



The six products we current promote and distribute for Pfizer and Baxter are primarily used for the treatment of cancer. According to Frost & Sullivan, driven by multiple factors, the number of new cancer cases in China increased from 4.0 million in 2015 to 4.4 million in 2019, and is expected to further increase to 5.7 million in 2030. According to Frost & Sullivan, China's oncology drug market reached RMB110.2 billion in 2015 and RMB182.7 billion in 2019, accounted for 9.0% and 11.2% of China's pharmaceutical market, respectively, and representing a CAGR of 13.5% from 2015 to 2019; in 2030, China's oncology drug market is expected to reach RMB659.8 billion, accounting for 19.7% of China's pharmaceutical market and representing an expected CAGR of 12.4% from 2019 to 2030. Such robust growth in oncology drug market in China's indicates the market potential for the products we promote and sell.

During the Track Record Period, we generated revenue from sales of promotion products for our business partners of RMB84.5 million, RMB211.4 million, RMB314.3 million, RMB222.6 million and RMB250.9 million, in 2017, 2018, 2019, and the first nine months in September 2019 and 2020, respectively, accounting for 7.0%, 15.0%, 18.4%, 17.2% and 15.8% of our revenue in 2017, 2018, 2019 and the first nine months in 2019 and 2020, respectively.

Our Sales of Pfizer Products

Under the Import and Service Agreement between Pfizer and Novamed, signed in July 2014, assumed by us pursuant to our acquisition of Novamed, and further supplemented in the Supplementary Agreements in May 2018 and April 2019, for a term until June 30, 2022, Pfizer appoints us as the exclusive importer, distributor and promotor for the products, Farlutal,

Methotrexate and Estracyt within Mainland China. The agreements can be renewed based on mutual agreement of both parties upon expiry. Salient terms of such agreements are listed below:

- **Nature of Rights**: Pfizer appoints us as its exclusive importer, distributor and promotor for the designated products in Mainland China.
- **Exclusivity**: Pfizer may not appoint any party other than us to import, distribute and promote the designated products in Mainland China. We may not sell the designated products outside Mainland China.
- **Pfizer's Obligations**: Pfizer's obligations include registration, product supply and other necessary supports.
- **Our Obligations**: Our obligations include import matters and related expenses, distributors and distribution channel management, bidding, hospital listing and product promotion.
- **Trademarks**: Pfizer grants us an exclusive, non-transferable license, to use the trademarks. Pfizer retains the ownership of such trademarks.
- **Inventory**: We are responsible for maintaining our inventory of the promotion products at a reasonable level as specified in the agreement.
- **Payment**: We pay Pfizer for ordered goods under agreed payment term and Pfizer pays us service fee calculated as we agreed upon.
- **Product Return**: Pfizer generally does not accept any return of goods supplied, unless there are quality issues identified by us and confirmed by the NMPA and/or other accredited drug quality inspection institutes.

Farlutal 法禄达

Farlutal is indicated for the treatment of breast cancer, carcinoma of the endometrium, prostate cancer and renal cancer. Farlutal is administered orally or parenterally in the recommended doses to women with adequate endogenous estrogen and transforms proliferative into secretory endometrium. Androgenic and anabolic effects have been noted, but the drug is apparently devoid of significant estrogenic activity. While parenterally administered Farlutal inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation, available data indicate that this does not occur when the usually recommended oral dosage is given as single daily doses. Pfizer is currently the MAH of Farlutal in the PRC. Farlutal was included in the NRDL since 2004.

Methotrexate 甲氨蝶呤注射液

Methotrexate is indicated for the treatment of acute leukemia, osteosarcoma and breast cancer. Methotrexate inhibits dihydrofolic acid reductase. Dihydrofolates must be reduced to tetrahydrofolates by this enzyme before they can be utilized as carriers of one-carbon groups in the synthesis of purine nucleotides and thymidylate. Therefore, methotrexate interferes with DNA synthesis, repair, and cellular replication. Actively proliferating tissues such as malignant cells, bone marrow, fetal cells, buccal and intestinal mucosa, and cells of the urinary bladder are in general more sensitive to this effect of Methotrexate. Methotrexate is currently registered under Pfizer pursuant to the NMPA in the PRC. Methotrexate was included in the NRDL since 2004.

Estracyt 艾去适

Estracyt is indicated for the treatment of hormone-resistant advanced prostate cancer. Estracyt taken orally is readily dephosphorylated during absorption, and the major metabolites in plasma are estramustine. Estramustine is metabolized into estrone and estradiol after absorption from the gastrointestinal tract, which is able to selectively penetrate into cells of the prostate and prostate tumor metastases. Besides, estramustine not only mainly inhibits microtubule function by binding to both tubulin and microtubule-associated proteins, but also depolymerizes cytoplasmic microtubules, leading to an inhibition of mitosis and induces cell apoptosis by disrupting the nuclear matrix. The metabolic urinary patterns of the estradiol moiety of Estracyt and estradiol itself are very similar, although the metabolites derived from Estracyt are excreted at a slower rate. Pfizer is currently the MAH of Estracyt in the PRC. Estracyt was included in the NRDL since 2009.

Our Sales of Baxter Products

Under the Product Promotion Agreement between us and Baxter, signed in January 2018 and valid until December 31, 2022, and the Drug Import and Distribution Agreement between us and Baxter (which we renew on an annual basis), signed in January 2020 and valid until December 31, 2020 (which, as of the Latest Practicable Date, was temporarily renewed to March 31, 2021 and was in the process of being formally renewed for another year starting from January 2021), we were granted by Baxter the exclusive right to promote the designated products, including Holoxan, Mesna and Endoxan, in hospitals in Mainland China, and the right to import and distribute the designated products in Mainland China. The agreements can be renewed based on mutual agreement of both parties upon expiry. Salient terms of such agreements are listed below:

- **Nature of Rights**: Baxter appoints us as its importer, distributor and exclusive promotor for the designated products in Mainland China.
- **Exclusivity**: Without our prior consent, Baxter may not appoint any party other than us to promote and sell the designated products in Mainland China. We shall not promote or sell competing products in Mainland China.
- **Baxter's Obligation**: Baxter shall be responsible for the regulatory registration of the designated products to be promoted by us with relevant regulatory authorities.
- **Our Obligation**: (i) As Baxter's designated importer and distributor in Mainland China, we are responsible for the import and distribution activities (such as bidding, delivery and revenue collection, and the engagement and management of sub-distributors) for the designated products in Mainland China. We shall not sell products outside Mainland China and shall not procure the designated products from parties other than Baxter for distribution in Mainland China. (ii) As Baxter's designated exclusive promotor in Mainland China, we are obligated to diligently promote the demand and sales of the designated products in Mainland China, including making relevant sales and marketing plans and informing Baxter regarding market conditions.
- **Intellectual Properties**: Baxter retains the ownership related to such agreements and grants us the right to use relevant intellectual property in order to fulfill our obligations under such agreements.

- **Product Supply and Storage**: Baxter shall be responsible for supply the designated products pursuant to relevant distribution agreements with us, and we shall be responsible for examining the supplied products upon receipt. We shall be responsible for providing services related to the import procedure, including obtaining relevant permits necessary for importing the designated products, the examination and custom clearance of the designated products, and we shall bear the relevant costs incurred. We shall be responsible for the storage of the designated products.
- **Inventory**: We are responsible for maintaining our inventory of the promotion products at a reasonable level as specified in the agreement.
- **Sales Target**: The annual sales target is set pursuant to negotiation between us and Baxter and shall be adjusted based on external regulatory and market fluctuation.
- **Payment**: Baxter shall pay us promotion fee in consideration for the promotional service we provide, on a per box basis and increased conditional on our successful completion of the sales target. We shall pay Baxter product supply price, as specified in the agreements and adjustable based on regulatory and market fluctuations, within 40 days of the supply of the designated products.
- **Product Recall**: Upon receipt of complaint of the designated products, we shall promptly evaluate the situation and notify Baxter for further rectification procedures, including possible product recall.
- **Product Return**: We shall conduct quality inspection of the products after custom clearance, and for products identified with quality issues, we have the right to demand product return or replacement from Baxter.

Holoxan 和乐生

Holoxan is indicated for bone and soft tumors, lymphoma, lung cancer, cervical cancer, ovarian cancer, testicular cancer and child solid tumors, bladder cancer, head and neck cancer and breast cancer. Holoxan is a prodrug that requires metabolic activation by hepatic cytochrome P450 isoenzymes to exert its cytotoxic activity. The exact mechanism of action of Holoxan has not been determined, but its cytotoxic action is primarily through DNA crosslinks caused by alkylation by the isophosphoramide mustard at guanine N-7 positions. The formation of inter- and intra-strand cross-links in the DNA results in cell death. Baxter is currently the MAH of Holoxan in the PRC. Holoxan was included in the NRDL since 2004.

Mesna 美司钠

Mesna is an organosulfur compound used as an adjuvant in cancer chemotherapy to detoxify urotoxic metabolites. Mesna reacts chemically with the urotoxic ifosfamide metabolites, acrolein and 4-hydroxy-ifosfamide, resulting in their detoxification. The first step in the detoxification process is the binding of Mesna to 4-hydroxy-ifosfamide forming a non-urotoxic 4-sulfoethylthioifosfamide. Mesna also binds to the double bonds of acrolein and to other urotoxic metabolites and inhibits their effects on the bladder. Baxter is currently the MAH of Mesna in the PRC. Mesna was included in the NRDL since 2004.

Endoxan 安道生

Endoxan is indicated for the treatment of breast cancer, lymphoma, ovarian cancer, small cell lung cancer and sarcoma. Endoxan is a widely used anticancer drug, immunosuppressant, and mobilizer of hematopoietic progenitor cells. Endoxan, as a prodrug, requires activation by CYP-catalyzed 4-hydroxylation, yielding cytotoxic phosphoramide mustard capable of reacting with DNA molecules to form crosslinks and lead to cell apoptosis and/or necrosis. Baxter is currently the MAH of Endoxan in the PRC. Endoxan was included in the NRDL since 2004.

PRODUCT DEVELOPMENT

For our proprietary and in-licensed pharmaceutical products, we actively engage in the development of such products. We focus on building up a drug portfolio with strong positioning in high-value and high-growth sectors. For the promotion products we sell for our business partners, we currently do not engage in any further product development activities.

We focus on clinical-need-based and market-oriented product development, which targets and identifies pharmaceuticals that have the potential for gaining widespread market acceptance within China's fastest growing, large and underserved therapeutic areas. As an integrated pharmaceutical company, we strive to build a portfolio of high-quality, differentiated products in established therapeutic areas that represent diseases and conditions that are most prevalent in China.

As of the Latest Practicable Date, we had launched one proprietary and two in-licensed drugs. In addition, we had a pipeline of eight candidates, five of which are drugs that have entered into pivotal clinical trials or more advanced stages.

In November 2020, the CDE promulgated the Clinical Technical Guideline for Conditional Approval of Drugs (Tentative) (《藥品附條件批准上市技術指導原則(試行)》). See "Regulatory Overview — Laws and Regulations in Relation to Drugs — Registration of Drugs". Under such guideline, pipeline drugs treating seriously life-threatening diseases with no existing effective treatments available may apply for conditional approval if its clinical trials have shown efficacy and if its clinical value can be predicted. As our pipeline products primarily focus on therapeutic areas such as oncology and severe infection with significant unmet medical needs in China, we believe, and the Industry Consultant, Frost & Sullivan, is of the view that such guideline may expedite our product development process.

In 2017, 2018, 2019, and the first nine months in 2019 and 2020, our total research and development expenses amounted to RMB82.7 million, RMB77.5 million, RMB87.7 million, RMB59.4 million and RMB48.7 million, respectively, representing 6.8%, 5.5%, 5.1%, 4.6% and 3.1% of our total revenue for the respective periods. See "Financial Information — Description of Major Components of Our Results of Operations — Research and Development Expenses" for further details of accounting policies relating to R&D costs.

Products Under Development

Our efforts in product development have yielded a pipeline of potential drug candidates in different stages of development spanning our key therapeutic areas. As of the Latest Practicable Date, we had a pipeline of eight drug candidates, five of which are late-stage drug products that have entered into pivotal clinical trial or more advanced stages, and three of which are early-stage drug products that have entered into Phase II clinical trial.

Pipeline Products

	Product Name	Mechanism of Action	Indication(s) / Clinical Adoptions	Partner	Date of Partnership Commencement	Commercial Rights	Our Contribution in China	Pre-Clinical / IND Filing / Phase I / Phase II / Phase III / NDA/BLA Filing / Marketed
Late-Stage	Oravig [1]	Lanosterol 14 α - demethylase inhibitor	Oropharyngeal candidiasis	Vectans Pharma (France)	June 2, 2008	10-year license from the date of first commercial sales in Mainland China, Hong Kong and Macau	Completed the phase III trial and obtained NMPA approval for commercialization	Marketed (Vectans Pharma); Commercialization expected in Q3-2021
Late-Stage	Vibativ (telavancin) [2]	Dual antibacterial activity on cell wall and cell membrane	HABP/VABP complicated skin and skin structure infections	Cumberland Pharma-ceuticals (USA)	May 21, 2015	15-year license from the date of first commercial sales in Mainland China, Hong Kong, Macau, Taiwan and Vietnam	Obtained IND and clinical trial waiver	Marketed (Cumberland Pharmaceuticals); Clinical trial waiver obtained; NDA submission expected in Q3-2021
Late-Stage	RRx-001 [3]	Myc inhibitor and antagonist of CD47-SIRPα pathway	Small cell lung cancer	EpicentRx,Inc. (USA)	June 30, 2020	10-year license from the date of first commercial sales in Mainland China, Hong Kong, Macau and Taiwan	Pre-IND conducted and in preparation of IND filing	US Phase III trial ongoing (Soligenix); US Phase III trial completion expected by the end of 2021
			Colorectal cancer					Combo with Irinotecan; US Phase II trial completed and Phase III trial launch expected in Q2-2021
Late-Stage	Naxitamab	Targeting GD2	High risk neuroblastoma	Y-mAbs Therapeutics, Inc. (USA)	December 17, 2020	license of an indefinite term from December 17, 2020 in Mainland China, Hong Kong, Macau and Taiwan	-	US Phase I and Phase II trials completed (Y-mAbs); Received approval fromFDAon BLA in November 2020[6]
Late-Stage	Omburtamab	Targeting B7-H3–expressing cells	CNS/ leptomeningeal metastasis from neuroblastoma	Y-mAbs Therapeutics, Inc. (USA)	December 17, 2020	license of an indefinite term from December 17, 2020 in Mainland China, Hong Kong, Macau and Taiwan	-	US Phase I and Phase II trials completed (Y-mAbs); Y-mAbs plans to refile BLA for Omburtamab in early 2021[6]
Early Stage	PEN-866 [4]	Mini-conjugate of HSP90-SN38	Solid tumors	Tarveda Therapeutics (USA)	March 17, 2020	20-year license from March 17, 2020 in Mainland China, Hong Kong, Macau and Taiwan	-	US Phase II basket trial ongoing (Tarveda Therapeutics); US Phase II trial completion expected in Q4-2022
Early Stage	PT-112	Platinum-containing compounds	Late stage prostate cancer	Phosplatin Therapeutics (USA)	May 26, 2015	15-year license from the date of first commercial sales in Mainland China, Hong Kong, Macau and Vietnam	Completed phase I and initiated phase II trial	US Phase II trial ongoing (Phosplatin Therapeutics); US Phase II trial completion expected in Q4-2021
			Cholangiocarcinoma					Combo with Gemcitabin; Phase II trial completion expected in Q4-2022
Early Stage	ABTL-0812	Akt/mTOR inhibitor	Endometrial cancer lung cancer pancreatic cancer	Ability Pharma (Spain)	April 22, 2016	15-year license from April 22, 2016 in Mainland China, Hong Kong, Macau, Taiwan and Vietnam	Obtained IND	EU Phase II trial ongoing (Ability Pharma); EU Phase II trial ongoing

China status [5] Partner's overseas status [5] Intend to utilize overseas clinical data for the NDA application in China

Abbreviations: Akt = Protein Kinase B; HABP = Hospital-acquired Bacterial Pneumonia; HSP90 = Heat Shock Protein 90; mTOR= Mammalian Target of Rapamycin; SN38 = 7-ethyl-10-hydroxycamptothecin; VABP = Ventilator-associated Bacterial and Pneumonia

Notes:

1. Our partner conducted Phase III and the earlier phases of the clinical trials. We obtained clinical waiver for clinical trials in China, and intend to conduct a bridging study for approval.
2. We conducted Phase III of the clinical trials, and our partner conducted the earlier phases of the clinical trials.
3. We expect to participate in the China portion of Phase III MRCT (Multi-Regional Clinical Trials) for Small Cell Lung Cancer in 2021 with EpicentRx.
4. We intend to join China portion of Phase III MRCT with Tarveda.
5. We are responsible for the clinical trials in China. Our partners are responsible for the clinical trials overseas.
6. Naxitamab and Omburtamab, both being biological products, are required to obtain BLA approval before commercialization. For both products, a Phase II clinical trial is adequate to serve as a pivotal trial in support of a BLA approval. As a result, as of the Latest Practicable Date, no Phase III clinical trial was intended or would be carried out for Naxitamab and Omburtamab.

Below is a description of our key drug candidates:

Products under Development — Late Stage

Oravig 诺弥可

We are developing a miconazole buccal tablet (MBT), Oravig, used to treat oropharyngeal candidiasis (OPC). Oravig has a broad-spectrum antifungal activity against the most frequent Candida observed in OPC, including *C. glabrata*, *C. krusei*, and *C. tropicalis*. It works at the cell membrane level by limiting ergosterol synthesis through inhibiting the cytochrome P450 14α-demethylase enzyme. Oravig also affects the synthesis of triglycerides and fatty acids and inhibits oxidative and peroxidative enzymes. MBT could provide the high and sustained levels of salivary miconazole concentrations, which would enhance its role as a local therapeutic alternative for OPC.

We have completed the registration trial and passed the data verification of the sampling test base by the NMPA in September 2019. We submitted the requested additional data for relevant technical review in June 2020 and received approval for the license in December 2020. In January 2021, we obtained the approval for the commercialization of Oravig in China from the NMPA.

According to Frost & Sullivan, the market of anti-fungal drugs in China, in terms of sales revenue, amounted to RMB25.5 billion in 2019 and represented a CAGR of 6.5% from 2015. The market is expected to grow at a CAGR of 3.3% from 2019 to 2024 and to reach RMB30.0 billion in 2024, and is expected to further grow at a CAGR of 4.1% from 2024 to 2030 and to reach RMB38.0 billion in 2030. As an imidazole anti-fungal drug, Oravig's market is expected to experience continuous growth in the future. According to Frost & Sullivan, Oravig has several advantageous features which would lead to its continuous long-term growth. First, Oravig can offer protection for wounded mucosa, which can reduce pain for the patients. Second, Oravig's small size, thickness and flexibility make it easier to be adopted by patients. Third, Oravig causes few drug interactions and resistance, which allows it to be applied in a broader patient base.

Under the License Agreement between BioAlliance and Novamed dated June 20, 2008, the Assignment and Assumption Agreement between Novamed and us dated June 10, 2016, the Assignment between Vectans Pharma and Onxeo S.A. dated May 12, 2017, and the Amendment to License Agreement we signed with Vectans Pharma on December 15, 2020 to affirm the foregoing assignments, pursuant to the contemplated transaction for a duration of 10 years of commercial sales, which is potentially renewable upon mutual agreement of the parties, Vectan grants us an exclusive, royalty-bearing license to promote, market, use, sell, offer for sale, and import Oravig in Mainland China, Hong Kong and Macau. Salient terms of such License Agreement are listed below:

- **Nature of Rights**: Vectans grants us an exclusive, royalty-bearing license to promote, market, use, sell, offer for sale, and import Oravig, and the right to use Oravig's related trademarks in Mainland China, Hong Kong and Macau.
- **Exclusivity**: Vectans shall not contract with any third party, or by itself, to develop, import, market, sell or distribute the product in the Mainland China, Hong Kong and Macau. Neither party shall contract with any third party to develop, manufacture, import, market, sell or distribute competing product.
- **Trademark Arrangement**: Vectans shall retain the ownership of the entire ownership interest in the trademark, and shall, at its own cost and expense, file and endeavors in good faith to obtain the registration of trademark in the Mainland China, Hong Kong and Macau.
- **Other Obligations**: We shall use reasonable efforts to assist Vectans locally in all aspects of regulatory approval and shall use reasonable efforts to commercialized the product for its approved indication following regulatory approval.
- **Quality Control**: The nature and quality of Oravig advised or sold by us on which it's related trademark appears shall conform to its product specification for packaging.
- **Supply**: Vectans shall be the exclusive supplier to us of Oravig during the term of the agreements. Vectans shall manufacture and supply to us such quantity of Oravig, in

finished form, as requested by us to cover the total market needs for Oravig. Vectans shall use commercially reasonable efforts to avoid shortfalls in supply of the products, and in the event that such shortfall cannot be avoided, shall promptly notify us and remedy the shortfall as soon as practicable.

- **Payment**: We shall pay Vectans (i) a non-refundable, non-creditable upfront fee in the low seven figures in US dollars, (ii) a regulatory milestone payment in the low seven figures in US dollars based on the obtention of the Market Authorization in Mainland China, (iii) a non-refundable, non-creditable payment based on sales performance and (iv) a percentage-wise royalty fee of low double digits based on net sales of product. As of the Latest Practicable Date, we have completed payment for the non-refundable and non-creditable upfront fee.

Vibativ

We are developing a rapidly bactericidal lipoglycopeptide antibiotic, Vibativ (telavancin), that is active against a range of clinically relevant Gram-positive pathogens. Vibativ is approved in the United States and Canada for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *S. aureus*. Vibativ is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby Vibativ both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. It has been shown to be effective against most isolates of *S. aureus* (including methicillin-resistant strains, or MRSA), *Streptococcus pyogenes*, *S. agalactiae*, *S. anginosus* group, *E. faecalis* (vancomycin-susceptible strains only). We obtained CDE drug clinical trial approval in August 2018. Moving forward, we need to first establish/define the local pathogens resistant/susceptible breakpoint, and then decide according to the test result whether it is necessary to conduct a small sample bridge test.

According to Frost & Sullivan, the market size of anti-MRSA infection antibacterial drug in China in 2019 was RMB4.1 billion, representing a CAGR of 10.2% from 2015. This market size is estimated to continuously increase at a CAGR of 10.4% from 2019 to 2024, and is estimated to reach RMB6.8 billion in 2024. It is estimated to further grow at a CAGR of 7.4% from 2024 to 2030 and to reach RMB10.4 billion in 2030.

Under the Development and Commercialization Agreement between Cumberland, as successor-in-interest to Theravance, and us dated May 21, 2015 and the Assignment Letter between Cumberland, Theravance, and us dated November 6, 2018, for a term of 15 years following the first commercial sales, which is renewable upon mutual agreement of the parties, Theravance grants us exclusive, sublicensable, transferable licenses under Theravance's patents, know-hows, and inventions in Mainland China, Hong Kong, Macau, Taiwan and Vietnam to develop, commercialize and manufacture Vibativ, and to use relevant trademarks to commercialize such product. Salient terms of such Development and Commercialization Agreement are listed below:

- **Nature of Rights**: Theravance grants us exclusive, sublicensable, transferable licenses in Mainland China, Hong Kong, Macau, Taiwan and Vietnam, to develop, commercialize and manufacture Vibativ, and to use relevant trademarks to commercialize such products.

- **Exclusivity and Competing Products**: We shall not make, develop, import, export, market, promote, distribute, offer for sale or sell a directly competing product during the term.
- **Patents and Trademarks**: Theravance (and as assumed by Cumberland) shall have the exclusive right and the obligation to prepare file, prosecute, maintain and extend relevant patents and trademarks, and shall own, and be responsible to precure, file and maintain trademark registration and bear relevant cost.
- **Other Obligations**: We shall use diligence efforts to develop and commercialize the product, and to seek applicable market authorization and approvals required to commercialize the product.
- **Supply**: Theravance (and as assumed by Cumberland) shall supply to us all of its requirement for formulated and vialed product for us to develop the product the licensed product in Mainland China, Hong Kong, Macau, Taiwan and Vietnam.
- **Payment**: We shall pay Theravance (and as assumed by Cumberland) (i) a one-time, non-refundable, non-creditable, upfront licensing fee in the low seven figures in US dollars, (ii) further milestone payments in the low seven figures in US dollars subject to obtaining marketing authorization approval in Mainland China, Hong Kong, Macau and Taiwan and (iii) additional transfer price as a percentage in the low double digits for the supply of products ordered by us for sales. As of the Latest Practicable Date, we have completed payment for the one-time, non-refundable and non-creditable upfront licensing fee.

RRx-001

We are developing a potential drug candidate, RRx-001, to treat various solid tumors. RRx-001 is a well-tolerated next generation small molecule immunotherapeutic that targets the CD47 — SIRPα axis and repolarizes tumor associated macrophages (TAMs) and other immunosuppressive cells in the tumor microenvironment to an immunostimulatory phenotype as well as improves tumor blood flow to enhance oxygen supply and drug delivery. It also has a pan-epigenetic activity which inhibits both DNA methyltransferases and DNA deacetylators, potentially resulting in expression of epigenetically silenced genes such as p53 through genomic DNA hypomethylation and reversal of chemoresistance. The preliminary results from a Phase II clinical trial (Quadruple Threat RRx001-211-01) of the sequential combination of RRx-001 and carboplatin or cisplatin plus another chemotherapy agent in patients with platinum-doublet refractory or resistant SCLC, $EGFR^+$ NSCLC, resistant/refractory epithelial ovarian cancer (EOC) and high-grade neuroendocrine tumors suggest "episensitization" or resensitization by epigenetic means to these chemotherapies. As an immunotherapeutic with a non-overlapping mechanism of action, which means that it can be used simultaneously with other therapies such as chemotherapy or immunotherapy, and the potential to convert treatment-resistant tumors into treatment sensitive tumors, RRx-001 may be used as monotherapy or in combination with chemotherapy, immunotherapy, radiation and targeted agents.

The data of SCLC in the third and further treatment population with the Quadruple Threat Phase II Study have been published in the British Journal of Cancer (BJC) in June 2019, which have

shown RRx-001 followed by the re-challenge with platinum plus etoposide chemotherapy is feasible and associated with promising results:

- **Efficacy**: Between December 2016 and March 2018, 26 patients were enrolled and received at least one dose of RRx-001. The median number of prior lines of therapy was two and 19 (73.1%) patients had platinum-resistant disease. In the intention-to-treat population, one (3.8%) patient achieved a partial response (PR) and seven (26.9%) patients had stable disease (SD) during treatment with RRx-001, whereas one (3.8%) patient had a complete response and six (23.1%) patients had a partial response on platinum plus etoposide. The estimated median and 12-month OS from enrollment were 8.6 months and 44.1%, respectively. The median PFS from the first dose of RRx-001 to trial discontinuation due to clinical or radiologic-based progressive disease on platinum plus etoposide or death was 7.5 months (95% CI: 5.8–NR), whereas the median PFS from platinum plus etoposide (PFS2) was 6.2 months (95% CI: 3.7–NR). In comparison, Nivolumab in second or third line SCLC treatment has been recently approved by the FDA with median OS as 4.4 months and median PFS as 1.4 months.
- **Safety**: The most common treatment-emergent adverse events from RRx-001 were mild discomfort at the infusion site (23%), decreased appetite (15.3%) and headache (11.5%), although none were considered related to RRx-001. There were four grade 3 or 4 toxicities, including decreased appetite, hypomagnesemia, hyperglycemia and musculoskeletal pain. Four patients (15.3%) developed suspected tumor pseudoprogression during RRx-001 treatment, associated with pain and tumor size increase by scans, which were followed by improvement in symptoms and either tumor stabilization or reduction with continued RRx-001 therapy.

Based on these initial results done by our partner, a randomized Phase III trial named REPLATINUM comparing RRx-001 followed by platinum plus etoposide to standard-of-care chemotherapy in treatment of third line or beyond SCLC patients has been initiated. We have decided to participate in this Phase III MRCT. We are currently preparing a pre-NDA meeting with CDE for regulatory approval in China, and we may engage in follow-up recruitment of patients for additional trials regarding cancers other than lung cancer.

Under the Exclusive License Agreement between us and EpicentRx, dated June 30, 2020, before the royalty term expires (on a product-by-product and region-by-region basis) and for a term of 10 years after first commercial sales, which is potentially renewable upon mutual agreement of the parties, EpicentRx grants us an exclusive, royalty-bearing license to develop, use, import, export (to any region within Mainland China, Hong Kong, Macau and Taiwan (for the purpose of the agreement including Mainland China, Hong Kong, Macau and Taiwan), sell, offer for sale, promote, market, distribute and commercialize the products in Mainland China, Hong Kong, Macau and Taiwan. Salient terms of such Exclusive License Agreement are listed below:

- **Nature of Rights**: EpicentRx grants us an exclusive, royalty-bearing license, solely to develop, use, import, export (to any region within the Mainland China, Hong Kong, Macau and Taiwan), sell, offer for sale, promote, market, distribute and commercialize the products for the Mainland China, Hong Kong, Macau and Taiwan.

- **Rights to Sub-license within Mainland China, Hong Kong, Macau and Taiwan**: We shall have the right to grant sub-licenses under the license to (i) an affiliate of us, or (ii) with EpicentRx's prior written consent, a third party (which sub-licenses shall not permit the further grant of sub-license) with whom we or our affiliate has a binding written agreement to collaborate on the development and commercialization of the RRx-001 products in the Mainland China, Hong Kong, Macau and Taiwan.
- **Supply**:
  - **Clinical Supply:** We shall purchase from EpicentRx our requirements of the applicable RRx-001 product for clinical use in the Mainland China, Hong Kong, Macau and Taiwan, at EpicentRx's manufacturing cost plus an agreed-upon premium, under a separate agreement to be entered into between the parties.
  - **Commercial Supply:** We shall discuss with EpicentRx in good faith the continued supply of the RRx-001 product by EpicentRx for our requirements of the applicable RRx-001 product for commercial use in the Mainland China, Hong Kong, Macau and Taiwan or the transition of such manufacturing responsibility to us.
- **Payment**: We have paid EpicentRx an undisclosed upfront payment and conditionally agree to invest in EpicentRx in 2020. EpicentRx is eligible to receive an aggregate amount of up to USD120 million upon achieving certain development, approval, and commercial milestones. In addition, EpicentRx is eligible to receive royalties within the range of 10% to 20% of sales of RRx-001 in Mainland China, Hong Kong, Macau and Taiwan.

Naxitamab

We have in-licensed an anti-GD2 antibody, Naxitamab, used to treat high risk neuroblastoma. In the U.S., Naxitamab is indicated in combination with granulocyte-macrophage colony-stimulating factor ("GM-CSF"), for the treatment of pediatric patients one year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. Naxitamab works through targeting GD2, a tumor antigen on the cell surface of neuroblastoma. Naxitamab prevails other GD2 targeting antibody-based therapies with its modest toxicity, shorter infusion time and ability to be administered in outpatient setting. Naxitamab has completed Phase I and Phase II trials in the U.S. and received approval from FDA on Biologics License Application ("BLA") in November 2020. We plan to utilize overseas clinical data for the NDA application in China for Naxitamab.

Under the License Agreement between us and Y-mAbs Therapeutics, Inc. ("Y-mAbs"), dated December 17, 2020, Y-mAbs grants us an exclusive, royalty-bearing, non-transferable, sublicensable license under Y-mAbs patent rights and know-how, to develop, research, use, make, have made, import, export, sell, offer for sale, promote, market, distribute and commercialize Naxitamab in Mainland China, Hong Kong, Macau and Taiwan. Salient terms of such License Agreement are listed below:

- **Nature of Rights**: Y-mAbs grants us an exclusive, royalty-bearing, non-transferable, sublicensable license in Mainland China, Hong Kong, Macau and Taiwan, to develop, research, use, make, have made, import, export, sell, offer for sale, promote, market, distribute and commercialize Naxitamab.

- **Patents and Trademarks**: Y-mAbs shall have the sole right, but not the obligation, at its own expense, to control the preparation, filing, prosecution and maintenance of the Y-mAbs patents and trademarks.
- **Other Obligations**: We (ourselves and through our affiliates and our respective sublicensees) shall be responsible for the development of, and shall exercise commercially reasonable efforts to develop the products in Mainland China, Hong Kong, Macau and Taiwan.
- **Quality Control**: The products delivered to us shall conform to the relevant product specifications and shall be manufactured, tested, stored, labeled, packaged and sold in accordance with the terms of the License Agreement and the applicable laws.
- **Supply**: Y-mAbs shall supply to us Naxitamab in finished product form, fully packaged and with labelling in accordance with the product specifications.
- **Payment**: We shall pay Y-mAbs (i) an upfront fee in the low eight figures in US dollars, (ii) separate regulatory milestone payments in the low eight figures in US dollars for obtaining regulatory approval and the BLA approval in Mainland China, (iii) commercial milestone payments in the mid seven figures or low eight figures in US dollars, based on our cumulative total net sales and (iv) a percentage-wise royalty fee of low double digits based on net sales of Naxitamab on a region-by-region basis.

Omburtamab

We plan to develop an anti-B7-H3 antibody, Omburtamab, used to treat CNS/ leptomeningeal metastasis from neuroblastoma. Omburtamab targets B7-H3–expressing cells in human solid tumors, including embryonal tumors, carcinomas, sarcomas, and brain tumors, and binds to an FG loop-dependent conformation on the B7-H3 molecule, a domain critical for its biologic function. Omburtamab has completed Phase I and Phase II trials in the U.S. and Y-mAbs plans to refile BLA for Omburtamab in early 2021. We plan to utilize overseas clinical data for the NDA application in China for Omburtamab.

Under the License Agreement between us and Y-mAbs, dated December 17, 2020, Y-mAbs grants us an exclusive, royalty-bearing, non-transferable, sublicensable license under Y-mAbs patent rights and know-how, to develop, research, use, make, have made, import, export, sell, offer for sale, promote, market, distribute and commercialize Omburtamab in Mainland China, Hong Kong, Macau and Taiwan. Salient terms of such License Agreement are listed below:

- **Nature of Rights**: Y-mAbs grants us an exclusive, royalty-bearing, non-transferable, sublicensable license in Mainland China, Hong Kong, Macau and Taiwan, to develop, research, use, make, have made, import, export, sell, offer for sale, promote, market, distribute and commercialize Omburtamab.
- **Patents and Trademarks**: Y-mAbs shall have the sole right, but not the obligation, at its own expense, to control the preparation, filing, prosecution and maintenance of the Y-mAbs patents and trademarks.
- **Other Obligations**: We (ourselves and through our affiliates and our respective sublicensees) shall be responsible for the development of, and shall exercise commercially reasonable efforts to develop the products in Mainland China, Hong Kong, Macau and Taiwan.

- **Quality Control**: The products delivered to us shall conform to the relevant product specifications and shall be manufactured, tested, stored, labeled, packaged and sold in accordance with the terms of the License Agreement and the applicable laws.
- **Supply**: Y-mAbs shall supply to us Omburtamab as an interim drug product (unlabeled antibody). We shall be responsible for the radio-labeling of Omburtamab in Mainland China, Hong Kong, Macau and Taiwan.
- **Payment**: We shall pay Y-mAbs (i) an upfront fee in the mid seven figures in US dollars, (ii) separate regulatory milestone payments in the mid seven figures in US dollars for obtaining the BLA approval in the first and second indication for Omburtamab in Mainland China, (iii) commercial milestone payments in the mid seven figures or low eight figures in US dollars, based on our cumulative total net sales and (iv) a percentage-wise royalty fee of low double digits based on net sales of Omburtamab on a region-by-region basis.

Products under Development — Early Stage

PEN-866

We are developing a potential drug candidate, PEN-866, to treat solid tumors. It is a new class of selective precision oncology medicines — penetrating solid tumors while minimizing damage to healthy tissue. PEN-866 is a small molecule drug conjugate that preferentially binds to the activated form of HSP90 in solid tumors and is linked to the topoisomerase 1 inhibitor (SN-38), a potent anti-cancer payload. PEN-866 is designed to accumulate and be retained in tumors. As the SN-38 payload is cleaved in the tumor over time, the sustained release of SN-38 in the tumor results in prolonged DNA damage and tumor regressions as demonstrated in multiple patient-derived and other xenograft tumor models. Based on its mechanism of inhibiting DNA synthesis and causing frequent DNA single-strand breaks, a combination treatment strategy would be feasible: such as PARP Inhibitor (to block DNA repair) with PEN-866 (to induce DNA damage). PEN-866 is the first-in-class small molecule drug conjugate from Tarveda's HSP90 binding drug conjugate platform.

Data from multiple pre-clinical patient-derived and xenograft tumor models clarified a specific biomarker to monitor the SN-38 driven DNA damage and also indicated a potential opportunity to combine with PARP inhibitors with greater efficacy than single agent. Phase I data with heavily treated/advanced stage patients showed early clinical benefit with a range of solid tumor and reasonable tolerance: Among the 17 evaluable patients, one achieved partial response (Squamous Cell Carcinoma of the Anus), four had stable disease. Most common AEs are GI related symptoms, fatigue and alopecia. Both autopsy and PK match with pre-clinical findings which demonstrated tumor uptake and retention of PEN-866 and intratumoral release of SN-38. The quick clearing from serum within 24 hours enables schedules of PEN-866 in combination therapy that avoids overlapping toxicity.

Based on these findings, further clinical development strategy includes a Phase II basket trial, rPh 2/3 single agent trials against current standard of care with SCLC, and Phase Ib/2I combination trials where PEN-866 containing regimen as a new standard of care.

For PEN-866, our partner, Tarveda Therapeutics, Inc. ("Tarveda") has initiated several Phase Ib-IIa clinical trials overseas, and we plan to participate in international multi-centered registration trials after the successful completion of Phase II trials conducted by Tarveda.

As a Small Molecule Drug Conjugates ("SMDCs") product, PEN-866 currently demonstrates strong potential, as currently the competitive landscape for the SMDCs market in China is largely undeveloped. According to Frost & Sullivan, as of September 30, 2020, there had been no approved SMDCs or ongoing clinical trials in China.

Under the Collaboration and License Agreement between us and Tarveda, dated March 17, 2020, for a term of 20 years, which is potentially renewable upon mutual agreement of the parties, Tarveda grants us an exclusive license to research, develop, use, offer for sale, import, export, and otherwise commercialize the PEN-866 product in Mainland China, Hong Kong, Macau and Taiwan. Salient terms of such Collaboration and License Agreement are listed below:

- **Nature of Rights**: Tarveda grants us an exclusive license to research, develop, use, offer for sale, import, export, and otherwise commercialize the PEN-866 product in Mainland China, Hong Kong, Macau and Taiwan.
- **Exclusivity and Competing Products**: We shall not, directly or indirectly, develop, manufacture, or commercialize competing product in Mainland China, Hong Kong, Macau and Taiwan.
- **Other Rights and Obligations**: We shall prepare development plan containing strategy, activities, study designs, timeline, study material needs and budget for the development of the compound and product under the agreement in Mainland China, Hong Kong, Macau and Taiwan. We shall have the right to conduct scientifically relevant pre-clinical studies to generate and obtain data that are reasonably useful for the development of licensed product in Mainland China, Hong Kong, Macau and Taiwan and have the right to control all aspects of the commercialization of the product. We are responsible, at our cost, for conducting all regulatory activities as required to obtain and maintain regulatory approval of licensed product in Mainland China, Hong Kong, Macau and Taiwan.
- **Supply**: Tarveda supplies our requirements of PEN-866 products for clinical use in Mainland China, Hong Kong, Macau and Taiwan, at Tarveda's manufacturing cost plus a percentage-wise administrative fee upon execution of a clinical supply agreement. Tarveda continues to supply or transition manufacturing responsibility to us, upon good faith negotiation with us, the PEN-866 products for commercial use.
- **Payment**: We shall pay Tarveda a one-time, non-refundable, non-creditable upfront fee in cash and shall have an upfront one-time right to invest in Tarveda in an equity financing. Subsequently, we shall pay Tarveda the one-time non-refundable, non-creditable payments subject to completion of project milestones. We shall also pay Tarveda non-creditable, non-refundable royalties on net sales and one-time non-refundable, non-creditable payments on achieving certain commercial milestone events. As of the Latest Practicable Date, we have completed payment for the one-time, non-refundable, non-creditable upfront fee and have completed our participation in Tarveda's equity financing.

PT-112

We are developing a potential drug candidate, PT-112, to treat solid tumors. Platinum-based chemotherapeutics such as cisplatin, carboplatin and oxaliplatin have been widely used for cancer treatment. However, platinum derivatives are associated with considerable toxicity and a high incidence of acquired resistance. PT-112 (phosphaplatin compounds) was developed with the specific aim of altering the cellular mechanisms of action of the drug to improve its efficacy while limiting its toxicity. PT-112 has improved pharmacokinetic and pharmacodynamic properties, including a considerable tendency to accumulate in the lung, liver and bones. PT-112 activates apoptosis signaling pathways with no nuclear DNA-binding and makes tumor cells apoptosis. The compounds are effective in both sensitive and drug resistant tumors. In addition, PT-112 induces the immunogenic death of cancer cells and hence stands out as a promising combinatorial partner of immune checkpoint blockers, especially for the treatment of immunologically cold tumors.

PT-112 is currently being evaluated in the U.S. by our licensor, Phosplatin, in three dose-finding, dose-confirmation and pharmacokinetic (PK) studies as (i) a monotherapy in patients with advanced solid tumors, under protocol PT-112-101, (ii) a monotherapy in patients with relapsed or refractory multiple myeloma, under protocol PT-112-102 and (iii) a combination with PD-LI inhibitor avelumab, supplied jointly from Merck Serono/Pfizer in patients with advanced solid tumors under protocol PT-112-103-PAVE-1. Clinical evidence of efficacy, together with safety data in those trials, showed good tolerance to treatment, justifying a positive benefit-risk balance and supporting initiation of Phase II studies to explore efficacy in specific indications or continued dose escalation to allow determination of the RP2D. In China, the enrollment of a Phase I/II study sponsored by us on PT-112 monotherapy in Chinese patients with solid tumors (Study SCI-PT112-ONC-PT-002) has been completed and the CSR became available in the third quarter of 2020. Meanwhile, another Phase I/II study of combination therapy with PT-112 and Gemcitabine is being conducted by us in China.

According to Frost & Sullivan, the sales revenue of platinum-based chemotherapeutics market in China was approximately RMB4.0 billion in 2019 and grew at a CAGR of 9.9% from 2015 to 2019; the sales revenue of platinum-based chemotherapeutics in China is expected to further grow to approximately RMB5.9 billion in 2024, representing a CAGR of 8.0% from 2019 to 2024, indicating considerable market potential for PT-112.

Under the Collaboration and Option Agreement between us and Phosplatin, dated May 26, 2015, for a term of 15 years after first commercial sales, which is potentially renewable upon mutual agreement of the parties, Phosplatin grants us an exclusive, royalty-bearing, nontransferable, sublicensable license under the Phosplatin technology, to research, develop, finish, use, sell, offer for sale, distribute and otherwise commercialize the PT-112 product in Mainland China, Hong Kong, Macau and Vietnam, with a potential option to extend such rights into South Korea and Taiwan. Salient terms of such Collaboration and License Agreement are listed below:

- **Nature of Rights**: Phosplatin grants us an exclusive, royalty-bearing, nontransferable, sublicensable license, to research, develop, finish, use, sell, offer for sale, distribute and otherwise commercialize the PT-112 product in Mainland China, Hong Kong, Macau and Vietnam.

- **Other Rights and Obligations**: Phosplatin grants us a non-exclusive, nontransferable, sublicensable license to perform clinical studies using the PT-112 product in oncology therapeutics and diagnostics, in Taiwan, South Korea, Australia and any other regions mutually-agreed in writing. We are also granted a non-exclusive license to manufacture the PT-112 product in Mainland China, Hong Kong, Macau for sale. We shall use diligent efforts to perform the development activities described in the development plan and shall have the sole right to implement commercialization activities in accordance with the commercialization plan. We shall own all regulatory filings and regulatory approvals for the product in Mainland China, Hong Kong, Macau and Vietnam, and be solely responsible for preparing regulatory filings for the product.
- **Supply**: Phosplatin shall manufacture the PT-112 product in finished form in unlabeled container in a final dosage form approved by the applicable regulatory authority in accordance with applicable specifications for the product. Phosplatin shall supply to us our requirements of the product for development activities and, if appropriate, for commercial activities under a separate Drug Supply Agreement to be negotiated.
- **Payment**: We shall pay Phosplatin (i) a one-time, non-refundable, non-credible upfront payment in the low seven figures in US dollars, (ii) several one-time, non-refundable non-creditable milestone payments in the low seven figures in US dollars following the completion of certain milestone events and (iii) royalty payments as a percentage of mid- to high-single digit on the net sales of the product in each country based on certain royalty rates. As of the Latest Practicable Date, we have completed payment for the one-time, non-refundable, non-creditable upfront fee and one of the several milestone payments.

ABTL-0812

We are developing a potential drug candidate, ABTL-0812, a first-in-class small molecule with anti-cancer activity through a unique mechanism of action. ABTL-0812 inhibits the PI3K/Akt/mTOR (PAM) pathway by binding to the nuclear receptors PPARα and γ, which induces TRIB3, a pseudo kinase that binds to Akt and impedes its activation, leading to mTOR inhibition and consequently to autophagy-dependent cancer cell death. The PAM pathway is responsible for the tumorigenesis of many cancers, including pancreatic cancer, as well as for the development of resistance to different treatments, such as chemotherapy.

For ABTL-0812, based on its safety and efficacy in pre-clinical models administered alone or in combination with chemotherapy, together with its excellent safety profile and signs of efficacy observed in a Phase I/Ib clinical trial, our partner, Ability is conducting Phase II clinical trial on endometrial cancer and pancreatic cancer overseas, and we plan to participate in international multi-centered registration trial on pancreatic cancer after the successful completion of Phase II trial conducted by Ability.

Under the Exclusive License Agreement between us and Ability, dated April 22, 2016, for a term of 15 years, which is potentially renewable upon mutual agreement of the parties, Ability grants us an exclusive license under Ability's patent rights and knowhows, to develop, use, offer for sale,

sell, import, export and commercialize the ABTL-0812 product, in Mainland China, Hong Kong, Macau, Taiwan and Vietnam. Salient terms of such Exclusive License Agreement are listed below:

- **Nature of Rights**: an exclusive license under Ability's patent rights and knowhows, to develop, use, offer for sale, sell, import, export and commercialize the ABTL-0812 product, in Mainland China, Hong Kong, Macau, Taiwan and Vietnam.
- **Other Rights and Obligations**: Ability grants us a co-exclusive license to manufacture the products in Mainland China, Hong Kong, Macau, Taiwan and Vietnam solely for development and commercialization of the products. Ability also grants us a sublicensable, fully-paid-up, royalty-free, co-exclusive license to use any and all trademarks related to the product.
- **Exclusivity and Competing Products**: Ability shall not grant any rights to any third parties to offer to sell, sell, import, export, or commercialize any ABTL-0812 product in Mainland China, Hong Kong, Macau, Taiwan and Vietnam. Neither party shall sell or distribute in Mainland China, Hong Kong, Macau, Taiwan and Vietnam directly competing products.
- **Payment**: We shall pay Ability (i) a one-time, non-refundable, non-creditable upfront payment, (ii) other one-time, non-refundable, non-creditable payments in consideration for research and development expenses to be incurred by Ability, (iii) milestone payments upon completion of certain milestone events, (iv) sub-license revenue if we sub-license to an unaffiliated third party and (v) royalty payment based on sales. As of the Latest Practicable Date, we have completed payment for the one-time, non-refundable, non-creditable upfront fee, and two of the milestone payments.

Our Product Development Focus

Our business has significantly benefited from our strong track record in product development. Our product development efforts primarily focus on the following therapeutic areas:

- **Oncology:** We actively seek to develop and commercialize products focusing on targeted therapies, immunotherapy and enhanced chemotherapy options with first-in-class or best-in-class potential.
- **Severe infection:** We focus on products with proven efficacy on severe infection caused by resistant bacteria environment, especially those cases caused by cross-contamination in the ICU and other hospital settings.

We carefully select product development programs based on market analysis and our scientific expertise. We strive to build up our product portfolio based on the strategy of strong positioning in high-value and high-growth sectors. We generally focus our product development efforts on therapeutic areas with significant unmet medical needs. Our product development activities are conducted both in-house and through collaborations with external CRO partners. See "— Collaboration with Outside Partners and Outsourced Product Development Activities."

Our Product Development Process

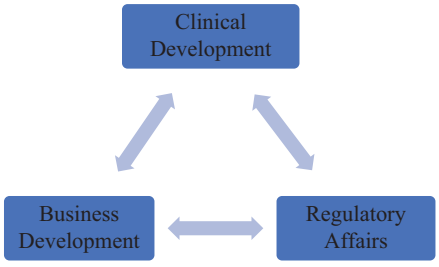
For our in-licensed products, we acquire licenses and are involved in the product development process for stages ranging from IND filing for some of our early-stage pipeline products to pivotal clinical trials for some of our late-stage pipeline products in China. Based on the joint development strategies of the products, we share responsibility for product research and development with our licensing partners in various kinds of arrangements.

Prior to the internal approval of each product development project, the project is first reviewed by our internal vetting team based on metrics related to its commercialization potential, such as clinical data, commercial data, correspondence with the regulators and the project development plan. Subsequently, our business development team prepares a business plan covering information such as potential indications, market size and valuation models. Our CEO office reviews the business plan and the valuation model, and our technical experts then conduct further due diligence as needed. Finally, our Board of Directors formally approves the contractual arrangement for such project, signifying the establishment of the in-licensing arrangement with our business partners and leading to our subsequent product development process.

After internal approval, our product development process typically involves following milestone stages:

- **Pre-clinical**: In the pre-clinical stage, our pre-clinical team evaluates the pre-clinical data of the products, provides professional opinions, and cooperates with partners to examine for long-term toxicology of drugs, to conduct biomarker and pharmacokinetics studies, and to implement relevant production processes based on project needs.
- **Investigational New Drugs** ("**IND**"): The IND declaration is prepared through the collaboration across our clinical development and regulatory affairs teams, and our regulatory affairs team is responsible for the submission of the IND application.
- **Phase I — III clinical trials**: The Phase I — III clinical trials are mainly coordinated by our clinical development team, who works closely with professional CRO teams. Our clinical development team has a well-developed SOP system and project management system to ensure that each of our clinical trials can be efficiently conducted and high-quality clinical trial data can be produced.
- **NDA and Launch**: After the completion of clinical Phase III development, our clinical development team coordinates with our regulatory affairs team to prepare for the application of NDA and cooperates with the marketing department to develop drug marketing strategies.

Our product development processes are carried out through the joint efforts and close collaboration across three teams within our Company:



- **Business Development Team**: Our business development team is headed by Ms. YU Zhongwen, who has over 15 years of experience in various positions including strategic planning and business development in the pharmaceutical industry. Our business development team proactively screens a broad scope of overseas assets and strives to identify valuable assets that can create high-value synergy with our existing product portfolio. The business development team also actively manages relationships with existing partners to accelerate product development strategies.
- **Clinical Development Team**: Our clinical development team is headed by Dr. GUO Xiaoning. See "Directors and Senior Management — Senior Management." Our clinical development team consists of our in-house clinical operating practitioners, who establish connections and collaborations with highly regarded local investigators for joint clinical trials and other development processes. Within the clinical development team, different smaller groups perform their respective functions, including pre-clical, medical affairs, clinical operations, site management, quality and product development and overseas study management, and these smaller groups coordinate together to perform our clinical development function. The ability of our clinical development team is evidenced by its proven track records of successfully completing registration trials in China.
- **Regulatory Affairs Team**: Our regulatory affairs team is headed by Mr. WU Lianzong. See "Directors and Senior Management — Senior Management." Working closely with our business development and clinical development teams, our regulatory affairs team implements effective registration strategies to minimize approval timeline and facilitate the approval process for the product candidates. Our regulatory affairs team possesses in-depth knowledge in the regulation system in China, as well as strong determination to accelerate product registration by actively seeking opportunities under regulation framework, both proven by their successful track record, including multiple fast-track designations and two clinical trial waivers granted since 2018.

Our In-house Product Development Teams and Capacity

As of September 30, 2020, our in-house product development teams consisted of more than 70 dedicated employees, and almost all of the management members of the product development teams held master's or higher degrees. We constantly recruit new talents from the market to our

product development team, and the composition of our product development team changes over the years. As of September 30, 2020, the management members of our product development teams on average had over 14 years of industry experience. The majority of our product development teams' members have experience working in multi-national pharmaceutical companies. In particular, Dr. GUO Xiaoning, vice president, the head of research and development department and the chief medical office of our Company, had 15 years of R&D experience in pharmaceutical MNCs, local pharmaceutical companies and renowned CROs. See "Directors and Senior Management – Senior Management."

Our product development teams strive to build the center of excellent operations, with additional functions in development strategies, medical monitoring, pharmacovigilance, and quality assurance to have the full in-house capabilities of managing large-scale local trials. Meanwhile, our product development teams also work closely to assist our business development team to assess and review new asset opportunities, and maximize asset commercial potential with accelerated development plan.

Collaboration with Outside Partners and Outsourced Product Development Activities

We collaborate closely with pharmaceutical companies, research institutions and universities to jointly carry out development of new pharmaceutical products, as well as to enhance our own product development capabilities. We have outsourced certain functions within our product development process, such as statistics and data management, to outside service providers. We select CRO vendors based on their expertise and quality of delivery as well as pricing comparison. We sign fee-for-service contracts with them and pay them by milestones of their professional deliverables. Our product development process is driven by the close cooperation between our in-house clinical operation team and our external CRO partners, based on a comprehensive, well-developed SOP system for clinical operations and a solid management system for clinical trial projects to ensure the efficient operation of the clinical studies. We are able to efficiently capitalize on the professional experience and knowledge skills of our CRO partners, in areas such as statistical analysis, data management, and laboratory testing, to ensure the high quality of clinical data obtained while keeping the costs under control.

SALES, MARKETING AND DISTRIBUTION

For our proprietary and in-licensed products, we derive demand primarily from hospitals and pharmacies through our sales and marketing activities. We sell our proprietary and in-licensed pharmaceutical products through distributors to hospitals and pharmacies.

For our sales of promotion products for business partners, we develop and maintain our collaboration with pharmaceutical companies such as our current partners Pfizer and Baxter, and we derive demand for the promotion products from hospitals and pharmacies through our sales and marketing activities. Our revenue from our sales of promotion products for business partners is derived from selling the promotion products through distributors to hospitals and pharmacies.

Sales and Marketing Activities and Commercialization Capabilities in China

Marketing Strategies and Commercialization Activities

Our marketing strategies focus on the combination of accumulating research evidence and the establishment of therapeutic guidelines. Our commercialization platform enables us to develop and market products, engage with customers and explore market opportunities.

We engage in a combination of offline and online marketing and promotional activities to explore and capture market opportunities. For our proprietary and in-licensed products, as well as the promotion products we sell for our business partners, we engage in offline marketing and promotional activities through our regular organization of and participation in marketing activities including academic conferences, expert meetings and consultation sessions, workshops and information sessions, national and local brand forums, and training sessions, which continuously enhance brand recognition for the products.

For sales and marketing efforts, we engage in the close alignment through functional teams to work together through the Area Alignment Committee ("AAC") to provide our customers and patients with integrated solutions at regional level. We have one AAC at each geographic region where we operate (including East China, Central China, North China and South China). See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China — Our Sales and Marketing Force." Our AAC at each geographic region generally consists of business units heads and functional team heads of the region, and makes decisions based on discussion and consensus among its members. With our innovative multi-channel marketing efforts, we push for innovative digital models to enhance stakeholder engagement, and improve operational efficiency and patient experience.

Our Sales and Marketing Force

For our proprietary product, in-licensed products and the promotion products we sell for business partners, our marketing strategies are implemented by our in-house sales and marketing team and are aligned across different therapeutic areas and geographic regions. Our in-house sales and marketing team generates market demand for the products among medical professionals primarily through its promotion efforts to enhance medical professionals' knowledge and understanding of the indications, clinical effects and advantages of our products.

As of September 30, 2020, our sales and marketing team included 616 employees deployed to cover approximately 2,170 hospitals in approximately 320 cities in China. We systematically deploy and manage our sales force to capture the latest market dynamics effectively. For example, we review the overall deployment of our sales force on a quarterly basis and track the planning and assignment of our medical representatives on a monthly basis. The following table illustrates the

number of our sales and marketing personnel, and the number of hospitals covered by geographic region in China as of September 30, 2020:

	Sales and Marketing Personnel					
Geographic Region	Business Unit — Immunology	Business Unit — Oncology	Total	Hospitals Covered	Number of Hospitals in Each Region[1]	Percentage of Hospitals Covered
East China (Office: Shanghai)	115	38	153	619	6,171	10.0%
Central China (Office: Hangzhou)	107	37	144	521	7,481	7.0%
North China (Office: Beijing)	115	47	162	501	12,012	4.2%
South China (Office: Guangzhou)	103	39	142	534	8,534	6.3%
Marketing Team	11	4	15	—	—	—
Total	451	165	616	2,175	34,198	6.4%

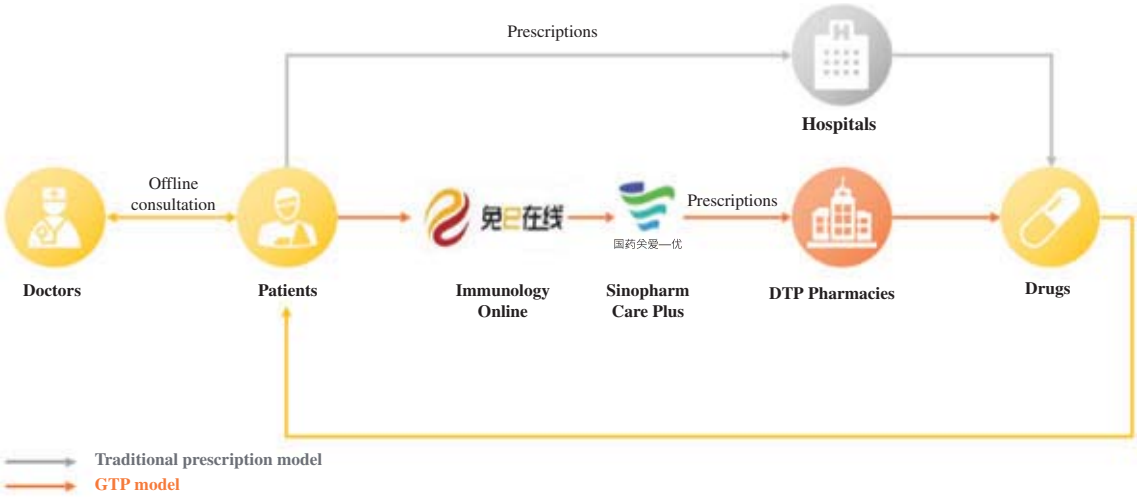
Note: (1) According to Frost & Sullivan, the number of hospitals in each region refers to the total number of comprehensive hospitals, hospitals of traditional Chinese medicine, hospitals of integrated traditional Chinese medicine and western medicine, minority hospitals, specialty hospitals, and nursing homes. The number of hospitals in each region is calculated by adding up the number of hospitals in each province within such region.

Our sales and marketing team consists of highly experienced personnel. Our sales and marketing team members are customer-focused and possess strong business acumen. We recruit our sales and marketing team members from the competitive talent market, with an emphasis on professional ethics and integrity, strong commitment and performance-driven mindset. The vast majority of them has a college degree or above with at least two years of industry experience. The majority of our senior sales managers had experience working in multi-national pharmaceutical companies. As of September 30, 2020, our sales directors, regional managers, district managers and medical representatives had on average approximately 18, 17, 14 and 10 years of industry experience, respectively.

We regularly provide in-house and external trainings to enhance the industry knowledge and marketing skills of our sales and marketing team. See "— Employees." We have also put in place measures and policies for our employees involved in sales and marketing activities. See "— Internal Control and Risk management."

Innovative Model: Go-To-Patient (GTP) strategy and platform

Collaborating with Sinopharm, in order to diversify our sales channels and promote Zadaxin's sales to patients through pharmacies, we piloted our GTP platform in 2015 which had since enhanced Zadaxin's accessibility to patients by extending the sales of Zadaxin beyond hospitals into pharmacies. We commenced to generate sales through this platform in 2018. In 2018, 2019, and the nine months ended September 30, 2020, sales volume through our GTP model contributed to more than 20%, more than 30% and more than 50% of our total sales volume of Zadaxin, signifying the increasing accessibility of Zadaxin to patients through pharmacies. The difference between the traditional prescription model and the GTP model in collaboration with Sinopharm is illustrated in the chart below:



In the traditional prescription model, patients go to hospitals to consult doctors, procure the prescriptions from hospitals, and purchase Zadaxin at hospitals based on their prescriptions. In contrast, in GTP model, after offline consultation with doctors and registration on our Immunology Online portal, patients can choose between:

(i) **Online Order and Delivery**:

Step 1: uploading their prescriptions obtained during doctor consultation to the Immunology Online portal;

Step 2: ordering Zadaxin online on the Sinopharm Care Plus platform, which coordinates with the DTP pharmacies to arrange for verification of patient information, payment and delivery of Zadaxin;

Step 3: having the DTP pharmacies deliver Zadaxin to them;

(ii) **Offline Purchase and Pickup:** patients can also purchase and pick up Zadaxin from DTP pharmacies based on their prescriptions obtained during doctor consultation.

As of December 31, 2017, 2018, 2019 and September 30, 2020, the number of DTP pharmacies supporting our sales of Zadaxin in China under the GTP model was 60, 65, 210 and 598, respectively.

The GTP model provides benefits for patients, doctors, hospitals, pharmacies and us. For patients, the GTP model offers them flexible means to purchase Zadaxin, enhancing the accessibility of Zadaxin. For doctors and hospitals, the GTP model separates healthcare services and drug sales,

thus enabling doctors to focus on the diagnosis and treatment of patients' diseases. For pharmacies, the GTP model enables an increase in drug sales revenue. For us, the GTP model successfully extends our sales beyond hospitals into pharmacies to diversify our sales channels and maximize patient reach.

Benefiting from the success of the GTP strategy for our sales of Zadaxin, we believe we are able to leverage the GTP model for the sales of other products in our portfolio and to capture future business opportunities.

Distribution in China

For our proprietary product, our in-licensed products, and the promotion products we sell for our business partners, we sell these products through distributors to hospitals and pharmacies. We select the distribution model that is the most suitable for the nature of our business and the products to be distributed, and we either engage third-party distributors, such as Sinopharm for the distribution of Zadaxin or Huizheng for the distribution of Angiomax, or use our own distribution network under SciClone Jiangsu for the distribution of promotion products for business partners, depending on factors such as geographic coverage, logistic facilities, and history of cooperations. For example, we engage Sinopharm for the distribution of Zadaxin as it can provide a broad geographic coverage and the cold chain logistic facilities needed for the distribution of Zadaxin, and we have been maintaining a track record of good collaborative relationship with Sinopharm for approximately 10 years; since our own sales and distribution network under SciClone Jiangsu currently does not have specialized distribution capacity for pharmaceutical products treating cardiovascular diseases, we engage Huizheng for the distribution of Angiomax as it can provide a broad distribution coverage for pharmaceutical products treating cardiovascular diseases. We believe our engagement of distributors and our current distribution model helps extend our geographic coverage in a cost-efficient manner while retaining proper control over our distribution network and marketing and promotion process.

Distribution Network for our Proprietary and In-licensed Products

For Zadaxin, we generate revenue through sales of products to Sinopharm. Sinopharm is one of the largest distributors of, and a leading provider of supply chain services for pharmaceutical and healthcare products and operates one of the largest pharmaceutical distribution networks in China. Sinopharm acts as our importer and distributor for Zadaxin in China, and we made such selection based on Sinopharm's scale, the scope of Sinopharm's national network coverage, and the quality of logistic services Sinopharm provides. Sinopharm sends purchase orders to us to purchase products from us, without any right of return except for replacement of products in the events of damaged products or quality control issues. As we bear the risk of loss during transit, revenue is not recognized until the shipment reaches its destination. In compliance with the "two-invoice system", after our sales of Zadaxin to Sinopharm, Sinopharm clears the products through customs of China as an imported drug and distributes further to hospitals and pharmacies.

We sell Zadaxin through Sinopharm to 31 provinces, municipalities and autonomous regions in China as of September 30, 2020. The distribution network through Sinopharm for Zadaxin had

reached approximately 1,130 class III hospitals, approximately 1,250 class II hospitals, approximately 720 pharmacies and approximately 3,560 other medical institutions in China as of September 30, 2020.

For Zadaxin, we entered into an import and distribution agreement with Sinopharm, which provides for annual automatic renewal and had been renewed annually during the Track Record Period. As of the Latest Practicable Date, we had renewed our import and distribution agreement with Sinopharm for the year ending December 31, 2021. Such import and distribution agreement provides distribution arrangements, such as the appointment of Sinopharm as the exclusive importer, specification of the territory for distribution, supply and delivery of the product, annual budget specifying the purchase amounts, credit terms and payment arrangements, Sinopharm's sales incentive payment, and other rights and obligations of both parties. Product price under the import and distribution agreement is set with reference to the end-point sales price at which the products are sold to hospitals or pharmacies, and is subject to future adjustments if such end-point sales price fluctuates to ensure the reasonable margin for Sinopharm. We are generally required to ship the products and issue invoice within 30 days upon receipt of purchase orders from Sinopharm. We grant Sinopharm a credit term of 90 days. In addition to Sinopharm's margin, we pay Sinopharm a fixed percentage amount as its importer sales incentive based on the scope of distribution services Sinopharm provides, and such importer sales incentive is evaluated on regular basis. Sinopharm is not allowed to import, distribute or sell in China any competing product of Zadaxin, including other products containing thymalfasin. We have the right, upon reasonable notice and during normal business hours, to inspect Sinopharm's business and records, and all facilities in which the products are being stored by Sinopharm. Damaged or non-conforming products, once detected by Sinopharm, can be either returned to us or destroyed. Either party has the right to terminate the agreement if the other party materially breaches the agreement or becomes insolvent.

We believe that we have been maintaining good collaboration with Sinopharm, and our relationship has been long-term, stable and mutually beneficial. We started engaging Sinopharm as our distributor for Zadaxin in 2011. During the Track Record Period, and since our start of collaboration with Sinopharm, there had been no instances in which we could not renew our import and distribution agreement with Sinopharm. Considering Zadaxin's market share in China, the margin of distribution and the fixed percentage importer sales incentive paid by us, the distribution of Zadaxin generates revenue for Sinopharm, which provides strong incentives for Sinopharm to maintain and enhance good business relationship with us, and to continue engaging in the distribution of Zadaxin. Consequently, we believe that it is unlikely that our relationship with Sinopharm will materially adversely change or terminate. To mitigate our reliance on Sinopharm, we have been diversifying our product portfolio and engage, or plan to engage, alternative distributors for distribution of other marketed products. Frost & Sullivan is of the view that alternative pharmaceutical distribution companies have similar distribution network coverage and comparable distribution costs to Sinopharm. However, for the distribution of Zadaxin in China, we do not expect to diversify our distribution arrangement by engaging with other distributors, since under the two-invoice system, we are only allowed to engage one importer for the import of Zadaxin into China, and our current arrangement with Sinopharm as our only distributor for Zadaxin makes it easy for us to manage and coordinate our distribution network of Zadaxin.

We do not have any direct contractual relationship with any distributors engaged by Sinopharm. In addition, according to our agreement with Sinopharm, we have access to the identity of distributors engaged by Sinopharm for Zadaxin. Sinopharm may consult us in administering the list of distributors. According to our arrangement with Sinopharm, Sinopharm is responsible for managing its distribution network to minimize cannibalization risk through means such as geographical exclusivity. We do not allow product return unless there is a product quality issue, which helps us to minimize channel stuffing risk. We monitor the inventory levels in the distribution network and we have the right to request Sinopharm to provide us with a detailed, accurate and complete written report of the current inventory level at the distributors engaged by Sinopharm. We review the performance of Sinopharm on a regular basis. Based on the results of our review, we may elect to continue, adjust or choose not to renew our distribution relationship with Sinopharm. As of December 31, 2017, 2018 and 2019 and September 30, 2020, Sinopharm's distribution network for Zadaxin comprised 97, 95, 101 and 104 distributors.

In 2017, 2018, 2019 and the nine months ended September 30, 2020, sales to our largest customer, in which Sinopharm owned more than 50% of the equity interest as of the Latest Practicable Date, accounted for 87.5%, 77.9%, 71.6% and 79.8% of our total sales, respectively. We have reliable business relationship with Sinopharm. None of our Directors, their respective associates or any person who, to the knowledge of our Directors, own 5% or more of the issued share capital of our Company have any interest in Sinopharm.

For Angiomax, on August 31, 2020, we entered into a Product Promotion Agreement with Huizheng, with a term of 10 years from August 31, 2020. Since our own sales and distribution network under SciClone Jiangsu currently does not have specialized distribution capacity for pharmaceutical products treating cardiovascular diseases, we engage Huizheng for the distribution of Angiomax as it can provide a broad distribution coverage for pharmaceutical products treating cardiovascular diseases. Under the agreement, Huizheng will promote and distribute Angiomax in Mainland China. Salient terms of the Product Promotion Agreement are set forth below:

- **Nature of Rights:** We appoint Huizheng as the exclusive importer, distributor and promoter for Angiomax in Mainland China. We pay Huizheng a service fee for the import, distribution and promotion service provided.
- **Minimum Sales Target:** Huizheng is required to meet the minimum sales target specified in the agreement to receive bonuses or avoid penalties.
- **Terms and Renewal:** 10 years, unless (i) terminated earlier pursuant to the terms of the agreement; or (ii) automatically extended for five more years, if volume-based procurement in Mainland China is expanded nationwide and covers bivalirudin before the end of the initial ten-year term. See "— Regulatory Regimes Affecting Prices of Pharmaceutical Products — Volume-based Procurement."
- **Termination Conditions:** The agreement can be terminated if mutually agreed between both parties, or by one party if the other party materially breaches the agreement.

In January 2021, we completed the transfer of IDL for Zometa, and became the MAH of Zometa in the PRC. Before December 2020, Zometa was sold through the existing distribution network by Novartis. Starting from December 2020, we began distributing Zometa in certain provinces in China through our distribution network under SciClone Jiangsu, and we expect to

complete the transition of the distribution of Zometa from the existing distribution network by Novartis to our distribution network under SciClone Jiangsu by the second or third quarter of 2021.

Distribution Network for Promotion Products for Business Partners

For the promotion products we sell for business partners, we import and distribute through SciClone Jiangsu. As of September 30, 2020, we had a nationwide distribution network for the promotion products we sell for business partners across 31 provinces, municipalities and autonomous regions in China. Our distribution network for the sales of promotion products for business partners had reached approximately 1,170 class III hospitals, approximately 2,020 class II hospitals, approximately 160 pharmacies and approximately 1,610 other medical institutions in China as of September 30, 2020.

For the promotion products we sell for our business partners, we are responsible for the overall management of our distributors, which includes screening, selecting, reviewing and risk management with respect to our distributors. We screen and select our distributors based on criteria including their industry track record, reputation, hospital coverage and other medical institution coverage, delivery capabilities, regional influence, infrastructure, financial condition, creditworthiness, and internal management.

We enter into a distribution agreement with each of our distributors, which provides for general terms for our distribution arrangement, such as the designated geographical area, amount for distribution, place and methods for delivery, inventory level management, credit terms, payment, and other rights and obligations. Product price under the distribution agreement is subject to adjustment, at our discretion, based on changes in the prevailing pricing arrangement resulted from the local competitive tender process. We are generally required to ship the products and issue invoice upon receipt of a distributor's order. We generally grant a distributor credit terms of 45 days. For each of our distributors, we hold 2% of its total sales value and pay back such amount quarterly if it pays for each order on time. Defect products, once detected, are deducted from the next shipment to such distributor. The agreement automatically renews for one year upon expiry, and we have the right to terminate the renewal of the agreement upon 30 days' advance notice.

Distributor Movement and Management

In order to optimize our product delivery and market coverage, we actively monitor the number of our distributors.

For the distribution of our proprietary product, Zadaxin, Sinopharm remains to be our only distributor in Mainland China with whom we have direct contractual relationship with.

For the promotion products we sell for our business partners and sales of DC Bead (which was discontinued on April 30, 2020), the following table sets forth the total number of our distributors as

of December 31, 2017, 2018 and 2019, and September 30, 2020, respectively, as well as the number of new distributors and the number of distributors whose distributorship was terminated during the periods indicated. The distributors we cooperate with are pharmaceutical distributors we select based on various factors including, among others, business qualification, management level, geographical coverage, business scale, and financial ability. In 2017, 2018 and 2019, the number of our distributors steadily increased, which was in line with the growth of our sales and our own business operations. The increase in the termination of distributors in 2019 was mainly due to termination of some of the distributors for DC Bead as part of the Company's efforts in optimizing its distribution network to improve efficiency; the increase in the termination of distributors in the nine months ended September 30, 2020 was mainly due to the termination of our sales of DC Bead.

	Year ended Dec. 31,			Nine months ended Sept. 30,
	2017	2018	2019	2020
As of the beginning of the period	2	62	146	166
Addition of new distributors	60	85	40	12
Number of distributors terminated during the period	0	1	20	32
Net increase in distributors	60	84	20	-20
As of the end of the period	62	146	166	146

According to our arrangement with distributors for our promotion products for business partners, each of such distributors is required to distribute within its designated areas. Therefore, such arrangement minimizes cannibalization risk. We do not allow product return unless there is a product quality issue, and such policy helps us to minimize channel stuffing risk. We monitor the inventory levels of such distributors through the inventory data they provide to us.

We review the performance of our distributors on a regular basis based on criteria including, among other things, their annual purchase amount, credit history, distribution capabilities, geographic location, length of business relationship with us and financial conditions. Based on the results of our review, we may elect to continue or enhance the existing distribution relationship, adjust the assigned distribution regions, and elect to continue, adjust or choose not to renew the contracts with those distributors who fail to meet our performance criteria.

To our best knowledge, during the Track Record Period, all of our distributors are Independent Third Parties.

International Marketing, Promotion, Sales and Distribution

Outside China, our proprietary product, Zadaxin, has been approved and is currently sold in countries such as South Korea, Thailand, Argentina, Italy, Cambodia, Singapore and Indonesia. We do not maintain an in-house team for overseas marketing, promotion, sales and distribution activities, and we primarily rely on our overseas business partners to handle the international marketing, promotion, sales and distribution of Zadaxin.

PRICING FOR PRODUCTS AND SERVICES

We sell our proprietary and in-licensed pharmaceutical products, as well as the promotion products we sell for business partners, to both public hospitals and public medical institutions, and alternative channels such as pharmacies, private hospitals and private medical institutions. Prices of pharmaceutical products sold to public hospitals and public medical institutions are affected by a series of regulatory regimes, such as the centralized tender process and volume-based procurement, while prices of pharmaceutical products sold to pharmacies, private hospitals and private medical institutions may not be subject to many of such regimes.

Regulatory Regimes Affecting Prices of Pharmaceutical Products

Centralized Tender Process

The Mechanism, Selection Criteria, Evaluation and Approval Procedures of the Centralized Tender Process

Prices of most pharmaceutical products in China, including all of our marketed products, sold to public hospitals and public medical institutions are determined through a competitive centralized tender process at the provincial or municipal level. The centralized tender process is held in different regions across China with varying terms and procedures. In the centralized tender process, we submit bids to supply our products to public hospitals and other public medical institutions at specified prices. Our bids are assessed by a committee consisted of pharmaceutical and medical experts, based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation, after-sale services and innovation. Generally, our products can be sold to public hospitals and public medical institutions in the relevant regions only if we have won the bids in the centralized tender process in the relevant regions. For details of the mechanism, selection criteria, evaluation and approval procedures of the centralized tender process, see "Regulatory Overview — Drug Purchase by Hospitals — Centralized Tender Process."

Participation in the Centralized Tender Process

Participation in the centralized tender process is voluntary. A pharmaceutical company can freely choose, for each of its products, to participate or not to participate in the centralized tender process depending on its business strategies, taking into consideration of various factors including the trade-off between price level and sales volume.

As of the Latest Practicable Date, our proprietary and in-licensed products, as well as the promotion products had generally participated in the centralized tender process. Specifically, for our proprietary product, Zadaxin, we selectively choose to participate in the centralized tender process in some provinces, while choose not to participate in the centralized tender process in other provinces, depending on our strategies in balancing price and sales volume based on the specific market conditions in each of the provinces.

Impact of the Centralized Tender Process on the Company

For each of our products, if we participate in the centralized tender process and win the bids, such products will be allowed to be sold to the public hospitals and other public medical institutions at the bid prices. In this case, we may need to adjust our prices accordingly in order to win the bids, while at the same time, we can enjoy the market opportunities in public hospitals and other public medical institutions, which will expand our sales volume.

If we do not participate or fail to win the bids in a centralized tender process in one or more regions, we will be unable to sell the relevant products to the public hospitals and other public medical institutions in those regions. As a result, our market share and revenue from public hospitals and public medical institutions could be adversely affected. See "Risk Factors — If we are unable to win bids to sell our proprietary product or in-licensed products to PRC public medical institutions through the centralized tender process, we will lose market share and our operations, revenue and profitability could be adversely affected." However, we may still sell our products in such regions through alternative channels such as pharmacies, private hospitals and private medical institutions. In such case, we may have more flexibility in maintaining a higher price of our products.

For our proprietary product, Zadaxin, we have made the decision whether to participate in the centralized tender process in each province depending on our strategies in balancing price and sales volume based on the specific market conditions in each of the provinces. Our commercial capabilities in selling through pharmacies, supported by our GTP model, has reduced our reliance on the traditional public hospital and public medical institution sales channels and allowed us to continuously drive sales growth without participating in the centralized tender process. See "— Sales, Marketing and Distribution — Sales and Marketing Activities and Commercialization Capabilities in China — Innovative Model: Go-To-Patient (GTP) strategy and platform." As a result, for provinces that we choose not to participate in or fail to win the bids in the centralized tender process, we believe we are able to endure short term decrease in revenue and maintain mid-to-long-term growth driven by the sales to pharmacies. For example, in Fujian Province, where we failed to win the bids for Zadaxin in the centralized tender process in 2016, the sales volume of Zadaxin to pharmacies, hospitals and other medical institutions decreased by approximately 12.1% in 2016 in comparison to 2015. However, such short-term decrease was followed by a strong recovery in the next three years driven by the sales to pharmacies. In 2017, 2018 and 2019, the total sales volume of Zadaxin to pharmacies, hospitals and other medical institutions in Fujian Province increased by approximately 24.0%, 35.4% and 17.6% in comparison to the preceeding years, respectively, and in such three years, the sales volume of Zadaxin through pharmacies accounted for approximately 60%, 68% and 71% of the total sales volume of Zadaxin in Fujian Province, respectively.

Since the participation in the centralized tender process is voluntary, our PRC Legal Advisor is of the view that the Company has the flexibility in adjusting its participation in the centralized tender process based on its strategies and business needs. Based on such flexibility of the Company in adjusting its participation and strategy, and the track record of the Company in successfully making such adjustments to optimize its results of operations and financial conditions, the Industry Consultant, Frost & Sullivan, is of the view that the centralized tender process is not expected to have a material adverse impact on the business, results of operations and financial conditions of the Company.

Volume-based Procurement

The Mechanism, Selection Criteria, Evaluation and Approval Procedures of Volume-based Procurement

In recent years, prices of certain pharmaceutical products in China sold to public hospitals and public medical institutions are affected by the volume-based procurement. Under the volume-based procurement, the Joint Procurement Office led by the National Healthcare Security Administration has issued a catalog containing varieties of compounds (drug generic names) to be covered by each batch of volume-based procurement. Selection of compounds to be included in such catalog is based on factors such as price level and NRDL coverage, as compounds with more in-depth NRDL coverage are prioritized to be included in the volume-based procurement to reduce the expense reimbursement pressure on national public medical insurance funds. Also, according to Frost & Sullivan, to ensure adequate competition, in practice the Joint Procurement Office would generally select a compound for which one innovative drug and at least two corresponding generic drugs that have passed the consistency evaluation are eligible to participate in the bid into the catalog.

For each compound that is included in such catalog, the domestic drug manufacturers and the domestic general agents for imported drugs in China are invited to bid to supply drugs under such compound to public hospitals and public medical institutions. Innovative drugs as well as generic drugs that have passed the consistency evaluation are allowed to participate in the bid for the volume-based procurement. The bids will be evaluated based on price as well as factors such as clinical efficacy, adverse reactions, and stability. Drugs that have won the bids in the volume-based procurement will be given priority in sales to public hospital and public medical institutions and are granted an agreed minimum procurement quantity, so they can gain greater sales volume at a usually lower price. In contrast, drugs that have failed to win the bids, or drugs that choose not to participate in the volume-based procurement may only be sold to public hospitals and public medical institutions at a suitable price through the centralized tender process pursuant to the relevant rules and regulations to capture the remaining market share of approximately 30%, which is the purchase volume beyond the agreed minimum procurement quantity for the bid-winning drugs allowed for other unselected products, as well as to pharmacies, private hospitals and private medical institutions. For details of the mechanism, selection criteria, evaluation and approval procedures of the volume-based procurement, see "Regulatory Overview — Drug Purchase by Hospitals — The Volume-based Procurement in "4+7 Cities" and Wider Areas."

Participation in Volume-based Procurement

Whether the compound for a specific drug is included in the volume-based procurement catalog and the frequency for updating the volume-based procurement catalog is determined by the Joint Procurement Office led by the National Healthcare Security Administration, and is beyond the control of pharmaceutical companies. However, for each drug under the compound included in the volume-based procurement catalog, participation in the volume-based procurement is voluntary.

Other than bivalirudin, the compound for our product Angiomax, as of the Latest Practicable Date, none of the compounds of our marketed products were included in the volume-based

procurement catalog, and therefore none of our marketed products were eligible to participate in the volume-based procurement. In the future, if any of the compounds of our marketed products is included in the volume-based procurement catalog, we may choose to participate or not to participate in the volume-based procurement based on our business strategy and our balancing of the trade-off between price and sales volume.

Impact of the Volume-based Procument on the Company

On December 25, 2020, the catalogs for four batches of volume-based procurement was released. Bivalirudin, the compound for our product Angiomax, was listed in the catalog for the fourth batch of volume-based procurement. We participated in the fourth batch of volume-based procurement for bivalirudin with Angiomax in February 2021, but Angiomax did not win the bid. See "Financial Information — Recent Development — Angiomax's status in the volume-based procurement." Other than bivalirudin, as of the Latest Practicable Date, none of the compounds of our marketed products were included in the volume-based procurement catalog. Therefore, as of the Latest Practicable Date, the volume-based procurement scheme had limited impact on our operations, revenue and profitability.

Specifically, for our proprietary product, Zadaxin, its corresponding compound, thymalfasin is only included in the work-related injury insurance catalog of the NRDL, and its corresponding reimbursement is limited to patients eligible for employment injury insurance. As of the Latest Practicable Date, thymalfasin was not listed in the NEDL either. In contrast, drugs with more in-depth NRDL coverage, such as those in Part A of the NRDL, or NEDL coverage, are expected to be given priority to be included into the volume-based procurement catalog. In addition, as of the Latest Practicable Date, only one generic thymalfasin drug had passed the consistency evaluation, while in practice the Joint Procurement Office would generally select a compound for which one innovative drug and at least two corresponding generic drugs that have passed the consistency evaluation are eligible to participate in the bid into the catalog. Based on the above, the Industry Consultant, Frost & Sullivan, is of the view that the likelihood for thymalfasin to be included in the volume-based procurement in the near future is low.

If thymalfasin is included in the volume-based procurement catalog, Zadaxin may face more intensive competition in sales to public hospitals and public medical institutions, and consequently, we and the Industry Consultant, Frost & Sullivan, believe that our business, results of operations and financial conditions will be adversely affected. For potential impact of the volume-based procurement on our Company, see "Risk Factors — We may experience difficulties in our sales efforts as a result of pricing regulations or other policies such as volume-based procurement that are intended to reduce healthcare costs, which could subject us to pricing and volume pressures and adversely affect our operations, revenue and profitability." However, we may formulate our optimal strategy and choose to participate or not to participate in the volume-based procurement depending on our balancing of various factors including the price level, sales volume and market shares, in similar ways as we formulate our strategy in participating in the centralized tender process. Since the participation in the volume-based procurement is voluntary, our PRC Legal Advisor is of the view that the Company has the flexibility in adjusting its participation in the volume-based procurement based on its strategies and business needs.

National Reimbursement Drug List

The Mechanism, Selection Criteria, Evaluation and Approval Procedures of the NRDL

Participants of the national public medical insurance programs and their employers, if any, are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of drugs included in the NRDL which sets forth the payment standard for drugs under the basic medical insurance, work-related injury insurance and maternity insurance funds. The National Healthcare Security Administration of the PRC, together with other government authorities, have the power to determine the drugs included in the NRDL, which is divided into two parts, Part A and Part B. For details of the mechanism, selection criteria, evaluation and approval procedures of the NRDL, see "Regulatory Overview — Laws and Regulations in Relation to the Coverage and Reimbursement — Medical Insurance Catalogue."

Participation in the NRDL

Whether the compound for a specific drug is included in the NRDL is determined by the relevant government authorities, and is beyond the control of pharmaceutical companies.

As of the Latest Practicable Date, Zadaxin was covered by the work-related injury insurance catalog of the NRDL, and the corresponding reimbursement was limited to patients eligible for employment injury insurance, while Zometa and the six promotion products we sell for our business partners were covered by the NRDL.

Impact of the NRDL on the Company

Since the NRDL coverage is based on the compounds rather than the specific drugs, the inclusion into, or the exclusion from, the NRDL, as well as other adjustments in the NRDL policies, are expected to have similar impacts on all drugs with the same compound. Therefore, our PRC Legal Advisor is of the view that changes in the NRDL coverage will have similar impacts on our products as on competitors to our products containing identical compounds, and the Industry Consultant, Frost & Sullivan, is of the view that changes in the NRDL coverage will not materially and adversely affect the competitive position of our products in comparison to that of their competitors containing identical compounds.

On December 25, 2020, the NRDL was updated, with 119 drugs newly added to and 29 drugs removed from the NRDL. See "Regulatory Overview — Laws and Regulations in Relation to the Coverage and Reimbursement — Medical Insurance Catalogue." The Company believes, and the Industry Consultant, Frost & Sullivan, is of the view, that none of the drugs added to or removed from the NRDL are direct competitors to Zadaxin or other marketed or pipeline products of the Company. Therefore, the Company believes, and the Industry Consultant, Frost & Sullivan is of the

view, that the updates to the NRDL on December 25, 2020 does not have material impact on the Company's business, results of operations and financial conditions, and is not expected to materially impact the Company's pricing or competitive strategies.

National Essential Drug List

The Mechanism, Selection Criteria, Evaluation and Approval Procedures of the NEDL

The NEDL is issued by the Ministry of Health and eight other ministries and commissions in the PRC, aiming at promoting essential drugs sold to patients at fair prices in the PRC and ensuring that the general public in the PRC has equal access to the essential drugs. Basic medical institutions funded by the government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the NEDL. The selection of drugs listed in the NEDL should be in accordance with the principles of necessity for prevention and treatment, safety and effectiveness, reasonable price, easy to use and clinical preference. For details of the mechanism, selection criteria, evaluation and approval procedures of the NEDL, see "Regulatory Overview — Laws and Regulations in Relation to the Coverage and Reimbursement — National Essent Drug List."

Participation in the NEDL

Whether the compound for a specific drug is included in the NEDL is determined by the relevant government authorities, and is beyond the control of pharmaceutical companies.

As of the Latest Practicable Date, among our marketed products, only Holoxan, Mesna and Endoxan were listed in the NEDL.

Impact of the NEDL on the Company

Since the NEDL coverage is based on the compounds rather than the specific drugs, the inclusion into, or the exclusion from, the NEDL, as well as other adjustments in the NEDL policies, are expected to have similar impacts on all drugs under the same compound. Therefore, our PRC Legal Advisor is of the view that changes in the NEDL coverage will have similar impacts on our products as on the competitors to our products containing identical compounds, and the Industry Consultant, Frost & Sullivan, is of the view that changes in the NEDL coverage will not materially and adversely affect the competitive position of our products in comparison to that of their competitors containing identical compounds.

Pricing for Proprietary and In-licensed Products

Our market access and commercial operation department is dedicated to closely monitoring new policies affecting the pricing of pharmaceutical products in China and formulating strategies to stay

competitive and profitable. We communicate with the local authorities in charge of the public tender process and study the tendering proposals to form a bid. We form a strategy to cope with competition in different provinces, with the goal of maintaining the price levels of the products and maximizing our overall sales in China.

During the Track Record Period, the prices of products we sell, such as Zadaxin, fluctuated due to factors including changes in reimbursement policies, changes in provincial and municipal centralized tender processes, and concerns over adjuvant therapies. See "— Products and Services — Our Proprietary products — Zadaxin 日达仙 — Financial Performance, Market Potentials and Effective Lifecycle Management." Our bidding and pricing strategies in the centralized tender process generally focuses on differentiating the products we sell instead of competing solely based on price. As we construct our product portfolio based on the strategy of positioning in high-value and high-growth sectors, we believe that we have developed a competitive advantage and are generally able to command a higher margin.

Pricing for Promotion Products for Business Partners

For our product sales for business partners, the pricing for the sales of such promotion products is determined through the same centralized tender process and subject to the same pricing regulations affecting our proprietary and in-licensed products.

PRODUCTION AND QUALITY CONTROL

For our proprietary and in-licensed pharmaceutical products, we produce all such products through outsourced CMOs. In addition, we procure certain raw materials including active pharmaceutical ingredients from outsourced raw materials CMOs for the production of our proprietary and in-licensed pharmaceutical products. Our production quality management system is fully aligned with the current GMP as implemented in markets that we operate in.

For the promotion products we sell for our business partners, we do not participate in the production of such products; instead, our business partners, Pfizer and Baxter, supply us with such products. We also adopt stringent quality management measures for the promotion product we sell for our business partners.

For further details regarding our material certificates, see "— Legal and Compliance — Licenses and Permits."

Production through CMOs

For our proprietary and in-licensed products, we outsource the production of such products to industry-leading, highly reputable CMOs. We outsource the production of Zadaxin to Patheon Italia, and the production of Zometa to Novartis. We are currently preparing the production plan for Angiomax and intend to outsource its production to Patheon Italia.

Our outsourced production of Zadaxin is conducted under the Manufacturing and Supply Agreement dated November 1, 2002 with Patheon Italia, a CMO known for its industry reputation and technical know-how in the aseptic manufacturing. Patheon Italia is an internationally renowned CMO providing drug manufacturing services for pharmaceutical customers internationally, which has multiple production facilities with experienced operators, and we believe that its production capacity is sufficient to meet our demand. We have worked with Patheon Italia since 2002. Salient terms of the Manufacturing and Supply Agreement are listed below:

- **Standard of Performance**: Patheon Italia shall manufacture and supply to us the products converted from API and other raw materials in accordance with our specifications and other applicable manufacturing requirements as contemplated under the agreement.
- **Delivery**: We may select the freight carrier used by Patheon Italia to ship products, and Patheon Italia shall be responsible for the loading of the products on departure and shall bear the risks and costs of such loading. Title and risk of loss or damage are transferred to us when Patheon Italia delivers products to the carrier for shipment.
- **Credit Term**: 30 days since the date of invoice, which should be issued for each delivery.
- **Quality Control**: We have 45 days upon receipt of products to inspect the products and confirm if any deviation from our specifications or other manufacturing requirements. Patheon Italia has 15 days to respond. If we cannot agree with Patheon Italia in another 10 days, an independent lab will be selected for evaluation of deviation. If Patheon Italia admits to the deviation or the independent lab certifies the deviation, we have the right to reject and return, at the expense of Patheon Italia, any portion of any shipment of products that deviates from our specifications or other manufacturing requirements.
- **Product Recalls and Returns**: If Patheon Italia fails to manufacture the products in accordance with our specifications and other applicable manufacturing requirements which results in a recall or return, Patheon Italia shall bear the cost and expense of such recall or return and use its best efforts to replace the recalled or returned products with new products within 60 days.
- **Audit**: We are provided with reasonable access to the production facilities and records of Patheon Italia for verification of its compliance with our specifications and other manufacturing requirements.
- **Term and Renewal**: Five years, with automatic renewal every two years upon expiry.
- **Termination**: Either party at its sole option may terminate this agreement upon written notice for cause under specified circumstances.

We are currently preparing the production plan for Angiomax and intend to outsource the production to Patheon Italia. We have communicated with our supplier in advance in accordance with our potential demands. A letter of intent for Angiomax manufacturing and supply was signed between us and Patheon Italia on December 17, 2019 and an amendment to existing Zadaxin manufacturing and supply agreement will be put in place to cover Angiomax soon.

Our outsourcing of the production of Zometa is conducted under the Supply Agreement dated February 25, 2020 with Novartis, from which we have licensed in Zometa. Novartis will supply us

with the products manufactured by Novartis, until we establish our own manufacturing and supply relationship with an international CMO. We intend to enter into a supply agreement and establish direct relationship with such international CMO in 2021. For the salient terms of the Supply Agreement, see "— Products and Services — Our In-licensed Products — Zometa 择泰."

We closely monitor production runs of our products and conduct our own quality assurance audit programs. We have adopted procedures to ensure that the equipment, facilities, processes, and operations of our CMOs comply with the relevant regulatory requirements and our internal guidelines. Our selection of CMOs are based on a number of factors, including their qualifications, relevant expertise, production capacity, GMP compliance, reputation, track record, product quality, reliability in meeting delivery schedules, and terms offered by them. To monitor and evaluate services performed by our CMOs, we set a series of specifications and manufacturing requirements, and review manufacturing related documents including batch records and analytical records to ensure the specifications and manufacturing requirements are met. In addition, we conduct onsite audit to make sure the CMOs' compliance with the GMP requirements and hold routine meetings with the CMOs for quality control purposes and engage in investigations when there is deviation from the process protocol, and/or master batch record. For more information regarding our quality control procedures for our CMO partners, see "— Quality Management."

We do not own any production facilities, nor do we have any planned capacity or production related technology. We do not intend at this time to acquire or establish our own dedicated manufacturing facilities for any of our products. By outsourcing our manufacturing activities, we can focus on core areas of competence such as drug candidate identification, product portfolio development and commercialization. With the potential launches of our late stage drug candidates in the near future and further product launches expected from our pipeline, we intend to continue collaborating with world-renowned, highly reputable CMO partners with whom we have long and established relationships. We believe that our current CMO partners for our products have enough manufacturing capacity to meet potential market demand. We also believe that we will be able to meet our market demand for our other drug candidates with our current CMO partners and through pursuing new relationships with additional CMO partners.

Manufacturing of pharmaceutical products is subject to extensive regulations that impose procedural and documentation requirements governing recordkeeping, manufacturing processes and controls, personnel, quality control, and quality assurance, among others. We are informed that the manufacturing process of our CMO partners are in compliance with the U.S. GMP and EU requirements under ICH standards which China also follows. In order to sell our Zadaxin product to the licensed importers in China, our CMO partners must be approved by the Italian Medicines Agency ("AIFA") and be accepted by the NMPA, the PRC regulatory agency, and we must obtain an IDL from the NMPA permitting the importation of our products into China. The license must be renewed every five years, and our next renewal for Zadaxin will be required in 2022.

Supply of Raw Materials and Products

For our proprietary and in-incensed products, we procure certain raw materials from our raw material CMO partners and deliver such raw materials to the CMOs for the production of final

products. Our current suppliers are primarily manufacturers of our APIs used for the manufacturing of our final products. For example, we rely on the industry-leading, highly reputable CMO, Polypeptide, to supply the API for our Zadaxin product. Polypeptide is a leading peptide manufacturer with expertise in commercial scale proprietary peptide manufacturing, and we have started working with Polypeptide since 1994. Other suppliers include the suppliers for the secondary packaging components for our drug products.

For the promotion products we sell for business partners, we are supplied with such finished products by our business partners, Pfizer and Baxter.

Supply of Raw Material for Proprietary and In-licensed Products

We carefully select our suppliers based on a number of factors, including their quality, technical know-how, industry reputation and GMP compliance with relevant regulatory agencies.

Our API for Zadaxin is manufactured and supplied by Polypeptide, a leading peptide manufacturer with global existence in France, Belgium, Sweden, India, and the U.S. Specifically, Zadaxin API is produced in the production site in Belgium (such site was formerly Lonza Braine SA ("Lonza") and was acquired by Polypeptide in 2016) as the primary site, and the U.S. as the secondary site to mitigate the supply risk. Our collaboration with Belgium site dated back to 1994 when the site was part of UCB-Biproducts SA. For the U.S. site, our collaboration started in 1998. Both Belgium and the U.S. site operations are fully compliant to EU and U.S. GMP, and we have adopted stringent measures to monitor and evaluate service performed. For our quality control procedures for our suppliers, see "— Quality Management."

Before Polypeptide acquired Lonza, we had two separate manufacturing and supply agreements with our API suppliers. The latest agreement with Lonza was entered into on April 30, 2014 while the latest agreement with polypeptide laboratories (the U.S. site) was entered into on June 23, 2014. After the acquisition of Lonza by Polypeptide, we entered into a new manufacturing and supply agreement covering both sites with Polypeptide on August 1, 2018. Salient terms of such agreement are listed below:

- **Standard of Performance**: Polypeptide shall manufacture and supply to us the API in accordance with our specifications and other applicable manufacturing requirements as contemplated under the agreement.
- **Delivery**: We shall arrange for shipment and take delivery of each batch of products from Polypeptide's facilities within 30 days after title and risk of loss are transferred to us.
- **Quality Control**: We have right to inspect the products and confirm if any deviation from our specifications or other manufacturing requirements. Polypeptide may request us to provide samples for testing. If discrepancy exists between the test results of ours and Polypeptide's, an independent lab will be selected for evaluation of deviation. If Polypeptide admits to the deviation or the independent lab certifies the deviation, we have the right to request replacement of the batch of products failing to conform with our specifications or other manufacturing requirements.

- **Audit**: Polypeptide shall provide us with annual product review reports within two months from the date of request which will include the status of products, summary of any changes in production processes, and summary of any critical and major deviations. We shall have the right to access the production facilities and records of Polypeptide for verification of its compliance with cGMP, our specifications and other manufacturing requirements.
- **Term and Renewal**: Five years, automatically renew for three year terms upon expiry.

The purchase price of our raw materials is primarily based on prevailing market prices for raw materials of similar quality. We believe such agreements with raw material suppliers provide us with stable supply of raw materials. During the Track Record Period, we did not experience any material price volatility or any significant supply shortage with regard to the raw materials we sourced from our suppliers, and therefore fluctuations in raw material costs did not have a material impact on our results of operations or gross profit margins during the Track Record Period. For the supply of our secondary packaging components, we order supplies and services on a purchase order basis.

Supply of Promotion Products We Sell for Business Partners

For the promotion products we sell for business partners, we are supplied with such products by our business partners, Pfizer and Baxter. We have entered into an import and service agreement with a term of three years with Pfizer, and a product promotion agreement with a term of five years and a drug import and distribution agreement with a term of one year, which is renewed annually, with Baxter. Our agreements with Pfizer and Baxter set out the specifications and prices for the products supplied to us, payment methods and guidelines for the sales and distribution of the products. We are granted the exclusive rights to import, distribute and promote Farlutal, Methotrexate and Estracyt of Pfizer, and the exclusive rights to promote, and the rights to import and distribute Holoxan, Mesna and Endoxan of Baxter in China. Pfizer and Baxter are responsible for the product supply, delivery and quality of the products, and we are responsible for import procedures, promotion and distribution of the products. We are granted credit terms of 30 to 60 days. We are generally allowed to return to Pfizer and Baxter the products with identified and confirmed quality issues. For the salient terms of such agreements, see "— Products and Services — Our Sales of Promotion Products for Business Partners."

Quality Management

We adopted stringent quality control measures for both of our proprietary and in-licensed products, and the promotion products we sell for business partners. We believe that an effective quality management system is critical to ensure the product quality, regulatory compliances, and maintain our reputation and success.

We have implemented a quality management system with a set of SOPs to manage the following aspects:

- **Product Quality**: We manage the quality of product, including APIs, final drug products, and printed labeling and packaging components. We approve and release APIs, packaging

components and final products and identify if our material and product specifications have been satisfied. We have a material review board to perform high level review of products with potential quality issues and make decisions to accept or reject the batches.

- **Process Monitoring**: We monitor the complaints and drug safety concerns to the products we sell and compliance with the cold chain storage requirements for our APIs and final products, and conduct annual product reviews. We track the complaints regarding the products we sell and perform investigations into our CMOs when necessary.
- **CMO Compliance Oversight**: We conduct audits of our CMOs and evaluate if any deviations or non-conformances to our specifications or manufacturing requirements occur from time to time. We take corrective and preventive actions when necessary and closely monitor any potential change of control to our CMOs. We identify, select and qualify our suppliers, and perform GMP audits to our CMOs to ensure their compliance.

Our quality assurance department consists of two employees based in the U.S. and Italy, respectively. Our quality assurance department is responsible to develop and maintain our quality management system and follow established procedures to manage manufacturing, testing, release and shipping of the products to ensure full compliance with the U.S., EU and PRC GMPs.

Key aspects of our quality control procedures are as follows:

Procurement and Raw Materials Quality Control

For our proprietary and in-licensed products, we procure raw materials including APIs and other materials used in our outsourced product manufacturing process only from approved suppliers. All approved suppliers are managed by our quality assurance department, which conducts supplier qualification evaluation on supplier candidates. We also regularly conduct on-site inspections and audits at key material suppliers' production facilities to ensure their compliance with GMP and other manufacturing requirements. We require provision of executed batch records, and analytical test data packet for review. Prior to batch release, we ensure the supplier QA unit has reviewed the entire batch record and resolved all associated deviation, and has provided the Certificate of Analysis and Certificate of Conformance. We perform the final batch disposition.

Final Product Quality Control

For our proprietary and in-licensed products, we monitor entire manufacturing process closely with regular quality assurance team meeting. Any major deviation related to the production of our products will be notified to us promptly and we are heavily involved in the investigation and root cause identification as well as the corrective and preventive actions. We have the right to conduct review of our CMOs' manufacturing operations and access any relevant records to assess their compliance with GMP and other quality assurance standards via document review and on site audit. Prior to batch release, we ensure the supplier QA unit has reviewed the entire batch record and

resolved all associated deviation, and has provided the Certificate of Analysis and Certificate of Conformance. We perform the final release and batch disposition. If the final product batch fails to meet our quality standards, it will be rejected.

Transportation, Logistics and Delivery Management

We have entered into a master services agreement for freight forwarding with an initial term of five years and automatic renewal for successive one-year periods, with SITTAM in Italy, and designated it as the agent/carrier for delivery of the final products. We are also responsible for delivery of raw materials, including APIs, to the CMOs for manufacturing of our final products. The shipping agents we select and use are specialized in pharma and cold chain shipping business and adhere to the GSP. For each shipment, temperature tracking devices are used and the temperatures are being recorded and reviewed. If there is any temperature excursion during the shipment, a deviation report will be produced and the product quality impact will be assessed. We are entitled to inspect our delivery service providers' facilities, equipment and procedures for quality assurance purposes. We have set pre-defined specifications for our delivery service providers as most of our delivery products require specific delivery conditions, including cold chain handling for the delivery of Zadaxin. We have a global stock throughout insurance policy to cover any potential loss of product in the storage and shipping.

Inventory Management

Our inventory consists primarily of final products and raw materials, including APIs, labels and packaging materials. We manage our inventory based on production forecast on a yearly basis, with updates each quarter. We update our inventory monthly, to maintain one-year storage of our APIs and one-quarter storage of our final products to ensure our inventory is above safety level. Our APIs are stored at -20°C temperature in our raw material CMO partners' warehouses, and our final products are stored at 2-8°C temperature in qualified warehouses in Italy. We have purchased stock throughput insurance to cover all our storages and shipping.

Product Recalls and Returns

We handle both mandatory and voluntary product recalls based on procedures and guidelines in compliance with the Measures on Drug Recall (《藥品召回管理辦法》). During the Track Record Period, we were not involved in any product recalls that had any material and adverse impact on our business, financial condition or results of operations. Consistent with customary industry practice in China, we generally do not allow product returns or exchanges.

SUPPLIERS

Under our product sales of our proprietary and in-licensed pharmaceutical products business, our suppliers generally consist of the CMO manufacturer for Zadaxin and the manufacturers of our

APIs used for the manufacturing of our final products. Under our sales of promotion products for business partners business, our suppliers are mainly Pfizer and Baxter, which supply us with finished promotion products we sell for them.

The tables below set out the details of our top five suppliers during the Track Record Period:

For the year ended December 31, 2017:

Suppliers	Purchase Amount (RMB'000)
Supplier A	82,029
Supplier B	36,457
Supplier C	43,329
Supplier D	24,829
Supplier E	14,252

For the year ended December 31, 2018:

Suppliers	Purchase Amount (RMB'000)
Supplier F	127,056
Supplier A	78,917
Supplier B	68,670
Supplier C	45,920
Supplier G	20,107

For the year ended December 31, 2019:

Suppliers	Purchase Amount (RMB'000)
Supplier F	188,615
Supplier C	87,116
Supplier A	78,941
Supplier B	24,148
Supplier D	15,799

For the nine months ended September 30, 2020:

Suppliers	Purchase Amount (RMB'000)
Supplier F	170,327
Supplier C	93,386
Supplier A	74,338
Supplier B	20,851
Supplier H	13,214

For the years ended December 31, 2017, 2018 and 2019 and the nine months ended September 30, 2020, purchases from our five largest suppliers accounted for approximately 50.7%, 61.9%, 63.4% and 67.6% of our total purchase amount, respectively. Purchases from our largest supplier accounted for approximately 20.7%, 23.1%, 30.3% and 30.9% of our total purchase amount in these periods, respectively.

To the knowledge of our Directors, none of our major customers are also our suppliers. To the knowledge of our Directors, none of our Directors or their respective associates or any person who to the knowledge of our Directors owned 5% or more of our issued share capital as of the Latest Practicable Date had any interest in any of our five largest suppliers for the Track Record Period.

CUSTOMERS

Under our product sales of our proprietary and in-licensed pharmaceutical products business, our direct customers generally consist of distributors for pharmaceutical products such as Sinopharm. Under our sales of promotion products for business partners business, our direct customers generally consist of distributors for pharmaceutical products. Under both our product sales of our proprietary and in-licensed pharmaceutical products business and sales of promotion products for business partners business, the end customers are hospitals and pharmacies.

The tables below set out the details of our top five customers during the Track Record Period:

For the year ended December 31, 2017:

Customers	Sales Amount (RMB'000)
Customer A[1]	1,061,748
Customer B	56,052
Customer C[1]	30,346
Customer D	27,823
Customer E[1]	15,675

For the year ended December 31, 2018:

Customers	Sales Amount (RMB'000)
Customer A[1]	1,097,648
Customer B	87,011
Customer F[1]	29,726
Customer G[2]	19,941
Customer H[2]	13,083

For the year ended December 31, 2019:

Customers	Sales Amount (RMB'000)
Customer I[(1)]	1,222,832
Customer B	83,233
Customer F[(1)]	39,101
Customer G[(2)]	25,730
Customer H[(2)]	17,193

For the nine months ended September 30, 2020:

Customers	Sales Amount (RMB'000)
Customer I[(1)]	1,264,580
Customer B	73,499
Customer G[(2)]	16,551
Customer F[(1)]	15,344
Customer H[(2)]	11,005

Note:

(1) Customer A, Customer C, Customer E, Customer F and Customer I are different operating entities under the Sinopharm group.

(2) Customer G and Customer H are different operating entities under the same group.

For the years ended December 31, 2017, 2018 and 2019 and the nine months ended September 30, 2020, sales to our five largest customers accounted for approximately 98.2%, 88.5%, 81.3% and 87.2% of our total sales, respectively. In the same periods, sales to our largest customer accounted for approximately 87.5%, 77.9%, 71.6% and 79.8% of our total sales, respectively.

The tables below set out the details of our five largest customers on a combined basis, with customers with more than 50% of equity interest owned by the same group combined together, to the best knowledge of our Directors, during the Track Record Period:

For the year ended December 31, 2017:

Customers	Sales Amount (RMB'000)
Sinopharm[(1)]	1,112,216
Customer B	56,052
Customer D	27,823
Customer J	8,953
Customer K	4,956

For the year ended December 31, 2018:

Customers	Sales Amount (RMB'000)
Sinopharm[1]	1,198,278
Customer B	87,011
Group X[2]	52,280
Group Y[3]	24,293
Group Z[4]	7,350

For the year ended December 31, 2019:

Customers	Sales Amount (RMB'000)
Sinopharm[1]	1,358,342
Customer B	83,233
Group X[2]	71,533
Group Y[3]	37,236
Group W[5]	12,004

For the nine months ended September 30, 2020:

Customers	Sales Amount (RMB'000)
Sinopharm[1]	1,369,671
Customer B	73,499
Group X[2]	52,591
Group Y[3]	27,605
Group Z[4]	8,250

Notes:

(1) including 46 customers in which Sinopharm owned more than 50% of the equity interest as of the Latest Practicable Date, including Customer A, Customer C, Customer E, Customer F and Customer I among our five largest customers, on the non-combined basis, during the Track Record Period

(2) including 18 customers in which Group X, a major pharmaceutical distribution company in China, owned more than 50% of the equity interest as of the Latest Practicable Date, including Customer G and Customer H among our five largest customers, on the non-combined basis, during the Track Record Period

(3) including 12 customers in which Group Y, a major pharmaceutical distribution company in China, owned more than 50% of the equity interest as of the Latest Practicable Date

(4) including three customers in which Group Z, a pharmaceutical distribution company in China, owned more than 50% of the equity interest as of the Latest Practicable Date

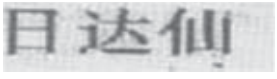
(5) including two customers in which Group W, a pharmaceutical distribution company in China, owned more than 50% of the equity interest as of the Latest Practicable Date

See "Risk Factors — We are dependent upon Sinopharm as the exclusive importer and distributor of Zadaxin; because of China's tiered method of importing and distributing finished pharmaceutical products, our results may vary substantially from one period to the next."

To the knowledge of our Directors, none of our major suppliers are also our customers. To the knowledge of our Directors, none of our Directors, their respective associates, or any person who to the knowledge of our Directors owned 5% or more of our issued share capital as of the Latest Practicable Date, had any interest in any of our five largest customers for the Track Record Period.

INTELLECTUAL PROPERTY RIGHTS

The Company's material intellectual property rights and patents[1] include:

Trademark	Place of Registration	Registered Owner	Class	Registration Number	Expiry Date (dd/mm/yyyy)
	China	SPIL	5	757875	27/7/2025
	China	SPIL	5	757877	27/7/2025
	China	SPIL	5	904614	27/11/2026
	China	SPIL	5	757876	27/7/2025
	China	SPIL	5	944610	13/2/2027

Patent Name	Patentee	Place of Registration	Application/ Registration Number	Application Date (dd/mm/yyyy)	Expiry Date (dd/mm/yyyy)
Thymosin Alpha 1 Peptide/Polymer Conjugates	SPIL	China	Registration No. ZL 02821872.8	01/11/2002	01/11/2022
Use of Thymosin Alpha 1 in The Preparation of Pharmaceutical Composition for Treating or Preventing an Aspergillus Infection in A Mammal	SPIL	China	Registration No. ZL 200480008490.4	29/03/2004	29/03/2024
Alpha Thymosin Peptides as Cancer Vaccine Adjuvants	SPIL	China	Registration No. ZL200580041799.8	06/12/2005	06/12/2025

Patent Name	Patentee	Place of Registration	Application/ Registration Number	Application Date (dd/mm/yyyy)	Expiry Date (dd/mm/yyyy)
Use of Thymosin Alpha 1 in The Preparation of Pharmaceutical Composition for Reducing Side Effects of Chemotherapy in Cancer Patients	SPIL	China	Registration No. ZL 01808907.0	19/04/2001	19/04/2021
Alpha Thymosin Peptides as Vaccine Enhancers	SPIL	China	Registration No. ZL201080030714.7	10/05/2010	10/05/2030

Note:

(1) As of the Latest Practicable Date, all of these material intellectual property rights and patents have completed their transfer from SciClone US to the Group. See "Relationship with Our Single Largest Shareholder — Independence from GL Capital Group — Operational Independence" and "Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of our Group" in Appendix V to this prospectus.

For details of our intellectual property, see "Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of our Group" in Appendix V to this prospectus.

We also follow procedures to ensure that we do not infringe the intellectual property rights of others. As of the Latest Practicable Date, we had not been involved in any significant intellectual property dispute or encountered major difficulties in enforcing our intellectual property rights in China.

See "— Internal Control and Risk Management — Intellectual Property Rights."

COMPETITION

Competition for Our Proprietary and In-licensed Products

For our proprietary and in-licensed products, we face competition from other pharmaceutical companies, including large, established pharmaceutical companies as well as some smaller emerging pharmaceutical companies. Our products primarily compete with products that are indicated for similar conditions as our products. We compete primarily on the basis of a series of factors, such as commercialization capabilities, product development capabilities, product clinical profile, quality, brand recognition, and price.

Competition for our Sales of Promotion Product for Business Partners

For products we sell for business partners, we face competition from other companies which provide product sales business for third party products. We compete primarily on the basis of a series of factors, such as commercialization capabilities, regulatory affairs capabilities, quality and price.

LAND AND PROPERTIES

As of the Latest Practicable Date, we did not have any self-owned properties. As of the Latest Practicable Date, we leased 12 properties in Mainland China and two properties in Hong Kong, with a total gross floor area of approximately 2,676 and 565 square meters, respectively. Our leased properties are primarily used as offices and the backup warehouse.

INTERNAL CONTROL AND RISK MANAGEMENT

We are dedicated to the establishment and maintenance of a robust internal control system. Since we were a public company listed on the NASDAQ until 2017, we have accumulated extensive experience in internal control and risk management as a public company. We have adopted and implemented risk management policies to address potential risks in relation to anti-bribery and anti-corruption, intellectual property rights, product quality management, distributor management, financial reporting, human resources, investment management and wealth management.

Our internal control system comprises our compliance department, finance department, human resource department, CEO office, and the corresponding departments for specific potential risks. Our Corporate Executive Committee comprised of the heads of each business department, and the Compliance Disciplinary Committee comprised of the heads of our immunology business unit, oncology business unit, human resource department, compliance department, our CFO and CEO. Our Corporate Executive Committee holds monthly meetings and all important operation related matters will be discussed and decided by the committee during the meetings. Our Compliance Disciplinary Committee also holds monthly meetings to discuss and decide on compliance related investigations and matters. For internal control related matters, the heads of business departments report to the CEO, and the CEO reports to our board of Directors.

Our internal control system and risk management measures include:

- **Anti-bribery and anti-corruption**: We have carried out various anti-bribery and anti-corruption measures, including the following:
  - **Global anti-bribery and anti-corruption policies**: We have implemented our global anti-bribery and anti-corruption policies with specific prohibition of bribes given to government officials, healthcare professionals, medical institutions and other objects of bribery. Such policies include, among others:
    - Prohibiting all of our employees and parties working on our behalf from making, offering to make, or promising to make any loan, gift, lavish trip or entertainment, donation or payment, or any other thing of value directly or indirectly, in cash or in kind, to or for the benefit of any official, including government officials and healthcare professionals, to obtain or retain business or to secure any improper advantage for us, whether or not any benefit is received.
    - Prohibiting financial benefit or benefit-in-kind (including loan, gift, lavish trip or entertainment, donation or payment, grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) provided or offered to a government official and/or healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering our products or for a commitment to continue to do so.

- Prohibiting payments in cash or cash equivalents to government officials and/or healthcare professionals, regardless of the purpose.
- Prohibiting the provision of entertainment and certain other leisure activities to government officials and/or healthcare professionals.
- Requiring written approval when an invitation to a government official or healthcare professional involves travel, sponsorship, entertainment, gifts, or speaker/consultant fees over a certain threshold amount.

- **Management of suppliers and customers and payment to third-parties**: We have implemented policies and SOPs regarding our procurement procedures, to manage various processes during procurement activities including pricing and quality control. We require new suppliers to provide detailed information regarding themselves. We provide training for our suppliers to ensure they comply with our anti-bribery and anti-corruption policies. We have also implemented stringent approval procedures for procurement activities, and require procurement personnel to compare suppliers and provide detailed information for obtaining such approval. We conduct anti-bribery due diligence over our customers, such as Sinopharm. We also provide training for some of our customers.
- **Procedures for charitable donations and academic promotion activities**: We have also implemented specific procedures for charitable donations and academic promotion activities and generally prohibited all facilitating payments whether legal or not. We have established periodic review on the list of speakers invited to our academic promotion activities to ensure related payments and expenses are in compliance with our policies. We also conduct detailed review of application for sponsorship of academic activities to ensure consistency with our sponsorship policies.
- **Employee expenses and reimbursement**: We have implemented stringent policies regarding employee expenses and reimbursement. Employees are required to use our system to submit expense reports for reimbursement. We require all business travels to be pre-approved by supervisors.
- **Record-keeping**: We have also maintained a record-keeping system for auditing and compliance purposes and established a whistleblower reporting system to create the reporting channel for suspected illegal activities. All our employees need to certify annually their compliance with our anti-bribery and anti-corruption policies and submit to our compliance department, and we conduct review to ensure that the reimbursed items accurately reflect the actual expenses. Employees who violate such policies will be subject to disciplinary measures accordingly. We also keep clear financial records to ensure that events and payments lacking legitimate business purposes can be timely identified and prevented.

- **Intellectual property rights**: We have engaged external legal counsel to manage all of our intellectual properties such as patents and trademarks. Our external counsel for intellectual property is experienced and well-equipped with knowledge and expertise to ensure our risks related to intellectual property is well under control. We have also established a system involving regular reporting to ensure we have adequate control over risks related to our intellectual property rights.

- **Product quality management**: See "— Production and Quality Control — Quality Management."
- **Distributor management**: See "— Sales, Marketing and Distribution — Distribution in China — Distributor Movement and Management."
- **Financial reporting**: Our finance team comprises a team of experienced professionals with appropriate qualifications. We have maintained adequate internal control over financial reporting in all financial reporting processes.
- **Human resources**: We mainly recruit through online recruiting platforms, our partnered headhunters, recruiting websites or our internal referrals. We conduct human resources department interview and additional rounds of business unit interview to ensure the quality of our new recruits. We offer regular and specialized training programs to satisfy the needs of our employees in different departments, including mandatory training programs related to compliance and company policies, and specialized trainings to satisfy the needs of each department or position. See "— Employees."
- **Investment management**: We follow stringent procedures to evaluate and approve investment projects. Our business development department is responsible for our acquisition and investment projects. To decide whether to invest in certain acquisition and investment projects, we mainly consider the assessment of net present value of the project based on forecast of its future cash flows, and the strategic impact the project may bring to our product line layout. For each project, we will undergo three phases prior to final execution:

  I. Project proposed, due diligence and negotiation of term sheet: Our business development department will propose the new project after initial evaluation of the project value, calculate the net present value of the project, negotiate collaboration model and term sheet with the counterparty, and be responsible for gathering market information and engage third-party institutions when needed. Our CEO and CFO will be involved for all discussion of important matters.

  II. Internal approval: After the term sheet is agreed upon, it will be submitted to our board of directors for approval. We will amend the term sheet with our counterparty if requested by the board.

  III. Agreement negotiation and execution: After the approval of term sheet by the board, we will negotiate the final agreement with the counterparty and may engage external lawyers if required. The agreement will be submitted for approval and execution after finalization.

- **Wealth management**: We arrange the use of our funds based on the preset monthly plans and invest in time deposits or wealth management products suitable for our business needs to generate reasonable gains. We in principle only invest in time deposits and wealth management products issued by state-owned banks or listed national banks, and our investment is limited to principal-protected products indicated in the contract terms. We

give priority to the products with higher yield while ensuring they could meet the liquidity requirement of our fund use plans. Any investment beyond the scope described above will need joint approvals by our CEO and CFO. We decide the investment principal and terms based on our fund use plans. Investment in time deposits exceeding RMB30 million or USD5 million in principal or with terms exceeding three months, and any investment in wealth management products will need approval by our CFO.

In addition to our strong internal control system and risk management measures, we have formed a culture of "high compliance and high performance" to ensure that we are in full compliance with laws and regulations in jurisdictions where we sell our products. With our internal control system and risk management measures, we are able to ensure that such compliance culture is embedded into everyday workflow and set the expectation for individual behaviors within our Company.

Risk Management in Response to the COVID-19 Outbreak

Outbreak of COVID-19

The recent outbreak of COVID-19 has materially and adversely affected the global economy. According to Frost & Sullivan, the global pharmaceutical industry had undergone challenges due to the outbreak of COVID-19, and such outbreak had impacted the global pharmaceutical industry in the following ways:

- **Clinical trials**: The impact of COVID-19 on the operation of hospitals had led to delays in clinical trials. The difficulties in recruiting new patients and accommodating patients for clinical trials had also created extra challenges.
- **Drug development process**: The drug development process could be delayed and interrupted due to delays in drug clinical trials. To overcome such challenges, pharmaceutical companies used artificial intelligence and big data platforms for gene sequencing, target discovery and drug development, which had increased the efficiency of drug development under the global outbreak of COVID-19.
- **Manufacturing and distribution**: The outbreak of COVID-19 had led to some restrictions in distribution channels. The adoption of automation technology in some pharmaceutical factories had revolutionized the production process to overcome challenges caused by the outbreak of COVID-19.
- **Marketing and sales**: The outbreak of COVID-19 had created challenges for sales representatives who need to visit hospitals and promote pharmaceutical products; as an alternative, virtual representatives and online academic meetings became more common, and they enabled pharmaceutical companies to provide patients with better services.

As of the Latest Practicable Date, our business, results of operations and financial conditions had not been materially affected by the outbreak of COVID-19. The outbreak of COVID-19 has had the following impact on our business, results of operations and financial condition:

- **Product sales and promotion activities**: The sales of Zadaxin increased as a result of the outbreak of COVID-19, as Tα1 (thymalfasin) had been listed for the treatment of severe and critical cases of COVID-19 according to the treatment guideline issued by NHC and National Administration of Traditional Chinese Medicine. Such increase was partially offset by the decreased number of hospital visits and operations by patients, since the outbreak of COVID-19 led many hospitals in China to allocate significant resources to contain COVID-19, and patients suffering from other diseases generally avoided going to hospitals in order to prevent being infected. For similar reasons, the sales and promotion activities of our promotion products for business partners had been adversely affected, leading to a lower rate of revenue growth for such products compared with that in previous years. As of the Latest Practicable Date, our sales activities had substantially resumed to normal.
- **Production and logistics**: The production process of our products had not been materially and adversely affected by the outbreak of COVID-19. Our CMO partners responsible for the production of our product had used certain level of automation in their production process to reduce their reliance on labor. As of the Latest Practicable Date, due to the adequacy of hygiene and sterilization measures, our CMO partners did not experience interruption in operations due to labor shortage. Moreover, the pharmaceutical industry had been subject to favorable and protective policies during the outbreak of COVID-19 to secure the production of pharmaceutical products, and our CMO partners could consequently operate as normal. The logistics for our products experienced certain delays due to the impediment in traffic and transportation during the global outbreak of COVID-19. For example, air freight was reduced during the COVID-19 outbreak due to the cancellation of flights. With the containment of COVID-19, such challenges in logistics and transportation had been largely resolved.
- **Supply of raw materials and promotion products**: We believe that our supply of raw materials had not been materially impacted by the outbreak of COVID-19, given that as a general practice, we maintain an adequate reserve of raw materials essential for the production of our product. See "— Production and Quality Control — Inventory Management." The supply of promotion products we sell for our business partners had not been materially and adversely affected either.
- **Product development**: Some of our product development projects were delayed due to various adverse factors caused by the outbreak of COVID-19, such as the difficulty in patient recruitment and enrolment process. However, such delays did not have a material adverse impact on our overall product development process. With the containment of COVID-19, the product development process of our product candidates has substantially resumed as normal.
- **Operations**: We have adopted a series of stringent disease prevention measures to reduce the risk of our employees contracting COVID-19. The measures implemented include, among others, workplace sterilization and ventilation, flexible working schedule

arrangements, monitoring and record keeping of employees' health conditions. As of the Latest Practicable Date, none of our employees had been infected of COVID-19.

As of the Latest Practicable Date, our promotion, sales and distribution arrangements, production activities, product development process and procurement process had substantially resumed to normal. In addition, we believe that the COVID-19 outbreak had not had any material impact on the implementation of our future plans and execution of our strategies. We have made various business contingency plans to maintain our profitability and ensure our normal operations during the COVID-19 outbreak.

Assuming the worst case scenario of the COVID-19 outbreak, in which:

(i) we cease all operations (including product sales, marketing and promotion, production by CMO partners, logistics and transportation, procurement of raw materials and promotion products, product development and other operational activities) from October 2020 onwards, as we will not earn or incur any revenue and costs, and we will only incur fixed expenses;

(ii) we make salaries payments to all of our current employees;

(iii) there are no other sources of funding except cash and cash equivalents and financial assets at fair value through profit or loss as of September 30, 2020;

(iv) we use 28.0% of the net proceeds from the Global Offering based on the low-end of the Offer Price range to repay existing debt, including our loan facility of USD$300.0 million with China Minsheng Banking Corp., Ltd. Hong Kong Branch, with a maturity date of November 4, 2024, and interest rate of LIBOR plus 2.3% per annum; and

(v) the settlement of trade receivables and trade payables is estimated on a prudent basis by taking into account our historical settlement patterns,

we would have sufficient cash flow for our business to remain financially viable for at least the next 17 months from September 30, 2020, which includes, but is not limited to the timely payment for the following:

- employees' salaries payments;
- lease payments;
- payments for existing purchase plans for long-term assets; and
- repayments of bank loans.

LEGAL AND COMPLIANCE

Licenses and Permits

We are subject to regular inspections, examinations, and audits for pharmaceutical businesses and are required to maintain or renew the necessary permits, licenses and certifications for our business. Our PRC Legal Advisor is of the view that we have obtained all material requisite licenses, permits and approvals for our operations in the PRC as of the Latest Practicable Date.

Legal Proceedings

We may from time to time become a party to legal or administrative proceedings, arising in the ordinary course of our business. During the Track Record Period and as of the Latest Practicable Date, we were not a party to any material litigation, claim, or administrative proceedings and no material litigation, claims, or administrative proceedings were known to our Directors to be pending or threatened against us.

SEC FCPA Investigation and Settlement

In August 2010, the U.S. Securities and Exchange Commission ("**SEC**") and the U.S. Department of Justice ("**DOJ**") commenced an investigation (the "**Investigation**") into SciClone US's potential violations of the Foreign Corrupt Practices Act ("**FCPA**") in conducting business in China (the "**Incident**"). Such Incident arose out of the allegation that employees of SciClone US's subsidiaries, who were primarily based in China, "from at least 2007 to 2012"[1], gave money, gifts and other things of value to government officials, including healthcare professionals employed at state-owned hospitals in China, in order to obtain sales of SciClone US's pharmaceutical products. Since the beginning of the Investigation, SciClone US had conducted a detailed, comprehensive internal review of the potential violations and its relevant internal control measures through a special committee. SciClone US had also communicated extensively and cooperated with the SEC and the DOJ through efforts including, without limitation, disclosure to the SEC and the DOJ of its internal investigation findings, voluntary reporting of possible misconducts and compliance issues identified, full and prompt responses to SEC's and the DOJ's enquiries, and participation in substantive presentations to the SEC and the DOJ.

In February 2016, SciClone US settled with the SEC pursuant to a cease-and-desist order (the "**Order**") published by the SEC, resolving the Investigation. Around the same time, the DOJ confirmed that it declined to pursue further action.

Pursuant to the terms of the Order, without admitting or denying any findings stated in the Order, SciClone US agreed to cease and desist from committing or causing any violations of the FCPA, to pay the SEC a total amount of approximately US$12.8 million (including US$9.426 million in disgorgement, US$900,000 in prejudgment interest and US$2.5 million in civil penalty, all of which were paid in February 2016, before the privatization), and to satisfy undertakings including providing periodic reports to the SEC for a prescribed term on status of its remediation and implementation of compliance measures, and providing a certification regarding its compliance with the undertakings.

After SciClone US had paid the requisite amount and fulfilled its undertakings under the Order, in June 2018, based on written confirmation from the SEC, the SEC's enforcement action was officially closed.

Note: 1. As stated in the Order.

SciClone US has taken proactive remedial measures to comply with the FCPA since the beginning of the Investigation. Remedial measures taken up to the SEC's case closure in June 2018 included (i) undertaking an extensive review of the policies and procedures on employee travel and entertainment reimbursements; (ii) substantially reducing the number of suppliers of travel and event planning services; (iii) improving policies and procedures on conducting necessary due diligence work to investigate the identity of third-party business partners, and the nature of payments made to such business partners; (iv) incorporating anti-corruption provisions in contracts; (v) providing anti-corruption training to travel and event planning vendors; (vi) disciplining employees (and their managers) who violated relevant policies; and (vii) recruiting and hiring a new management team in China that emphasizes and reinforces the culture of compliance.

After the case closure, we have continued to strengthen our internal control measures to ensure compliance with relevant laws and regulations. Among other steps taken, we have continued to implement applicable existing compliance measures, and have further refined our global anti-bribery and anti-corruption policies underlining the prohibition of bribes given to government officials, healthcare professionals, medical institutions and other objects of bribery. For our existing anti-bribery and anti-corruption measures, see "— Internal Control and Risk Management — Anti-bribery and anti-corruption." Since our implementation of the enhanced internal control measures, to our best knowledge, there has been no recurrence of similar incidents involving alledged bribe-giving conduct by our employees in violation of applicable anti-bribery and anti-corruption laws and regulations.

Since the beginning of the Investigation, as part of our persistent efforts to prioritize compliance on all levels, we have also undergone substantial changes in corporate structure, with new board members, new management and new shareholders. See "History, Reorganization and Corporate Structure — Material Development Milestones" and "Directors and Senior Management." For example, in 2013, we hired Mr. ZHAO Hong, our current President and CEO, who delivered strong message of compliance to sales team and business units through various channels such as sales meetings and public announcements. Such changes were also evidenced by the establishment of two committees, namely (1) Global Compliance Committee, which was responsible for establishing general compliance objectives and policy direction and communicating with the Audit Committee on compliance achievements and strategy, and (2) the Compliance and Disciplinary Committee, which was responsible for executing and implementing compliance policies, training, monitoring the internal control and disciplining employees for violations of policies. As of the Latest Practicable Date, none of the persons who served as directors or executive officers of SciClone US during the period of alleged FCPA violations under the Investigation held any position at the Company.

We have engaged Protiviti Shanghai Co., Ltd. ("Protiviti"), an independent internal control consultant to conduct a special review on the effectiveness of internal control addressing the risks of bribe-giving. Protiviti conducted the review during July and August 2020 on the design and implementation of the relevant polices against bribe-giving, and examined, on a sample basis, evidences of control activities in the period from January 1, 2018 to April 30, 2020. Protiviti's work procedures encompassed the Company's (i) anti-bribery control environment, (ii) vendor/third-party payments, (iii) employee reimbursement, (iv) payments to salespersons, and (v) pricing, discounts

and other payments to distributors/agents/customers. Based on the results of the review, no significant issue had been identified and therefore Protiviti confirmed that the relevant internal control was effective, adequately designed and duly implemented. Protiviti further confirmed that the relevant internal control, if persistently and duly implemented and practiced by relevant employees as designed, is effective and adequate in addressing the risks of bribe-giving. See "— Internal Control and Risk Management — Anti-bribery and anti-corruption."

On the basis that (i) the closure of SEC's enforcement action; (ii) SciClone US has taken proactive remedial measures to comply with the FCPA since the beginning of the Investigation; (iii) we have engaged Protiviti to conduct a special review on the effectiveness of our internal control measures regarding bribe-giving, and have adopted the enhanced internal control measures to ensure ongoing compliance; and (iv) there has been no known recurrence of similar incidents since our implementation of the enhanced internal control measures, our Directors are of the view that our internal control measures are adequate and effective to prevent occurrence of similar incidents in the future.

Based on the above, including (i) the view of the Directors, and (ii) the special review performed by Protiviti and the results reported thereof, nothing has come to the Joint Sponsors' attention that would reasonably cause them to believe that the relevant internal control measures, if persistently and duly implemented and practiced by relevant employees as designed, would not be effective and adequate in addressing the risks of bribe-giving.

EMPLOYEES

As of September 30, 2020, we had 797 full-time employees, including 786 located in the PRC, eight located in Hong Kong, one located in the United States, one located in Italy, and one located in the Cayman Islands. The table below sets forth a breakdown of our employees by business function as of September 30, 2020:

	Number of Employees	Percentage
Marketing, Promotion and Sales	659	82.7%
Product Development	79	9.9%
Others	59	7.4%
Total	797	100.0%

We believe that our success depends in part on our ability to attract, recruit and retain quality employees. We recruit our employees through a combination of different methods, including job application through online recruiting platforms, internal referral by our current employees, and recommendations from headhunters. Our recruitment is based on a number of factors, including candidates' work experience and educational background and our vacancies.

To maintain the quality, knowledge and skill levels of our workforce, we provide our employees with periodic trainings, including general trainings that cover areas such as firm culture,

workplace safety, information technology, data security, and other logistics aspects, as well as specific trainings that improve employee knowledge and expertise in certain important areas related to our business. We believe that such training programs have enhanced the productivity of our employees.

The remuneration package for our employee generally includes salary and bonus. We conduct periodic performance reviews for our employees, and their remuneration is performance-based. We also reward outstanding talents among our employees with incentive such as stocks plans and options, as well as with awards and honors to recognize their contributions to the Company. Our employees also receive welfare benefits including medical care, housing fund, pension, and other benefits. As required by applicable PRC regulations, we participate in various employee benefit plans that are organized by the government, including social security insurance and housing provident fund. Our Directors believe that we maintain a good relationship with our employees.

INSURANCE

We maintain property loss insurance, employer liability insurance, product liability insurance, stock throughput insurance and clinical trial liability insurance that we believe are in accordance with the relevant laws and regulations in China. We do not carry any business interruption or any key person insurance, which are not mandatory under the PRC laws. See "Risk Factors — Risks Relating to Our Business and Industry — We may be subject to product liability lawsuits, and our insurance may be inadequate to cover damages" for further details of risks relating to our current insurance coverage. Our Directors are of the view that our current insurance coverage is in line with industry practice and is adequate for our operations.

ENVIRONMENTAL MATTERS, SOCIAL RESPONSIBILITY AND GOVERNANCE

We are subject to environmental protection and occupational health and safety laws and regulations. As we did not own manufacturing facilities or product development facilities during the Track Record Period, we did not incur material environmental protection expenses during such period. During the Track Record Period and as of the Latest Practicable Date, we complied with the relevant environmental protection and occupational health and safety laws and regulations in China, and we did not have any incidents or complaints that had a material and adverse impact on our business, financial condition or results of operations during the same period.

We have formulated visions and goals to meet high standards in environmental, social, and governance aspects. We focus on areas such as public health social responsibility and have planned various activities to fulfill such responsibility. To fulfill our social responsibility and to mitigate inequality in medical resources, we are active in participating in charitable donation to regions with limited medical resources. For example, in December 2016, we made donation with value of RMB500,000 to Pu'er City, Yunnan Lancang Lahu Autonomous County and the Menglian Dai Lahu and Yi Autonomous County through the poverty alleviation project by Huangpu District of Shanghai.

We had also been actively observing our social responsibility during the COVID-19 outbreak. Our contribution and corporate social responsibility efforts in response to the COVID-19 outbreak include:

(i) donating charitable funds designated for the treatment of COVID-19 to Wuhan Charity Federation;

(iii) donating our Zadaxin to foundations, hospitals and medical institutions, including, among others, Wuhan Red Cross Foundation, Chen Xiaoping Foundation for the Development of Science and Technology of Hubei Province, West China Hospital of Sichuan University, Sichuan University, Zhong Nanshan Medical Foundation of Guangdong, Shanghai Public Health Clinical Center, The Second Hospital of Nanjing (Public Medical Center of Nanjing) and The First Hospital of Harbin Medical University;

(iii) supporting clinical trial projects in response to the outbreak of COVID-19; and

(iv) hosting and participating in academic events studying the treatment and containment of COVID-19.

As part of our governance effort, we strive to provide a safe working environment for our employees. We have implemented workplace safety guidelines setting out safety practices, accident prevention and accident reporting. We organize workplace safety trainings such as fire emergency training in order to protect the workplace safety of our employees.

We also endeavor to adhere to good governance practice by following our culture of "high compliance and high performance." Our internal policies and SOPs, including our anti-bribery policies ensure that our internal control system is adequate to safeguard our compliance with relevant laws and regulations. See "— Internal Control and Risk Management."